IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	**REDACTED PUBLIC VERSION FILED JANUARY 10, 2024** C.A. No. 21-691-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW [redacted]

DEFENDANT'S REPLY IN SUPPORT OF ITS
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I. AVADEL'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT NO. 1 – INVALIDITY OF ASSERTED CLAIMS OF SUSTAINED RELEASE PATENTS FOR LACK OF WRITTEN DESCRIPTION

Jazz's opposition attempts to manufacture factual disputes where there are none, by mischaracterizing the substance of the claims and the legal standards for written description.

A. The Asserted Claims of the Sustained Release Patents Encompass an Enormous Number of Potential Formulations

There is no dispute as to the salient inquiry: "For genus claims, which are present here, we have 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). Against that backdrop, Jazz's Opposition is predicated on a false construct. Jazz asserts that "[t]he ingredients Avadel focuses on . . . are not components of the inventive functional coating described for controlling release of drug in the SR Specification. Instead, they are part of the CR core." Jazz Opp. Br. at 2-3 (emphasis omitted) (footnote omitted). That baldly distorts the specification, which discloses a vast genus of potential formulations, which can include countless combinations of the wide array of potential excipients disclosed, combined together into various dosage forms—including most prominently, tablets. The claims at issue—formulations including a sustained release portion with a core and a functional coating that includes 20-50% methylacrylic acid-methyl methylacrylate co-polymer ("MAMM"), an immediate release portion, and a GHB release profile measured using specific test apparatus—represent a mere speck in the total universe of formulations contemplated by the specification.

The "Detailed Description" in the specification kicks off with no mention of the alleged "inventive functional coating." Jazz Opp. Br. at 2. Instead, it begins by stating that "[f]ormulations and dosage forms for the controlled release of a drug are described herein," which in one embodiment "is provided as a coated tablet." Ex. 1 at 3:66-4:9. The notion of a functional coating

is not a requisite according to the specification; rather, "***[i]n certain embodiments***, the controlled release formulations described herein are provided as a coated tablet composition having a controlled release core coated by a functional overcoat." *Id*. at 9:31-34.[1] Far from mandating the claimed dissolution testing methodology, the specification recites various possibilities: tests "using a standard USP type 2 or USP type 7 dissolution apparatus" and various dissolution media, including "purified water, 0.l N HCl, simulated intestinal fluid, and others." *Id*. at 7:64-8:4.

The bulk of the specification is devoted to describing particular embodiments "[w]here the controlled release formulations described herein are formulated as a coated tablet having a controlled release core (CR core)." Ex. 1 at 9:46-48. The next passage describes various possibilities for "the amount of drug included in a CR core." *Id*. at 9:56-10:14. The specification then describes embodiments involving the weight of the active relative to the weight of the CR core. *Id*. at 10:15-29. The specification proceeds to describe embodiments in which "the controlled release dosage form comprises a CR core that includes drug substance in combination with one or more excipients, such as binders, fillers, diluents, disintegrants, colorants, buffering agents, coatings, surfactants, wetting agents, lubricants, glidants, or other suitable excipients." *Id*. at 10:30-35. That discussion continues from col. 10, ln. 35 through col. 11, ln. 52. The specification then states: "Where the controlled release formulations as described herein are provided as a coated tablet composition, the CR core is coated with a functional coating." *Id*. at 11:54-56. Thus, the description of the huge number of excipients that can be used in the CR core are at the heart of the specification—including for formulations with a functional coating.

[1] Emphasis is added throughout, unless otherwise noted.

Even if the functional coating limitation is considered in isolation (as Jazz does, improperly), the specification discloses numerous other polymers, pore formers,[2] plasticizers, and anti-tack agents that could be included in the functional coating in addition to the MAMM Jazz elected to include in the claims. Br. at 6. This is significant, because the claims only require 20-50% by weight of MAMM in the functional coating, meaning that the claims encompass formulations with functional coatings containing up to 80% by weight of a combination of excipients other than MAMM. As a result, despite Jazz's protests to the contrary, there is no material dispute that the specification describes a broad genus encompassing an enormous number of formulations.

B. There Are No Blaze Marks for the Claimed Formulations

The fundamental flaw in Jazz's approach is that it starts with the claims, and then searches the specification for written description of individual claim limitations. That is legal error. In *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013),[3] the patentee, like Jazz does here, argued that the claims were supported by an adequate written description because the specification "provides formal textual support for each individual limitation recited in the claims." *Id.* The Federal Circuit held that this approach was improper, because by "[w]orking backward from a knowledge of [the claims], that is by hindsight," it is "all very clear what route one would travel through the forest of the specification to arrive at [the claimed invention]." *Id.* But when "viewing the matter from the proper vantage point of one with

[2] As Avadel explained in its opening brief, the specification lists four categories of pore formers. Br. at 8. At his deposition, Dr. Charman identified three of them, but inadvertently failed to include the described "small-molecule pore formers." CoF 6, A1524, 356:22-358:6. For the purposes of this motion, even if the scope of potential pore formers is limited the three from the specification that Dr. Charman identified, the number of potential pore formers available for a POSA to select from would be significant. Br. at 8-9.

[3] Avadel relied on *Novozymes* in its opening brief, Br. at 11, but Jazz failed to address it at all.

no foreknowledge," the claims lacked "meaningful support in the written description." *Id*. (internal citations omitted) The Federal Circuit further held that:

> Taking each claim—as we must—as an integrated whole rather than as a collection of independent limitations, one searches the 2000 application 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.

Id. The *Novozymes* decision is on all fours. When considering the claims "as an integrated whole," there is no genuine dispute that the specification contains nothing to specifically guide a POSA to use MAMM as an excipient, let alone in combination with the claimed dissolution profile. It is undisputed that (a) none of the examples include MAMM, (b) pore formers in general are entirely optional, and (c) the specification discloses potential issues with enteric pore formers. *See* SMF ¶¶ A-10, A-11, A-12 and Pltf's. Resp. thereto.

Jazz highlights certain portions of the specification, because it assumes that a POSA has already chosen to pursue formulations with a pH sensitive start-up lag time—but fails to offer any blaze marks guiding the POSA in this direction. Jazz Opp. Br. at 8 ("***if*** a pH sensitive start-up lag time is 'desired,' then the SR Specification directs a POSA to use one of only three enteric materials, including MAMM co-polymers").[4] Dr. Moreton conceded that the specification would not direct a POSA to a formulation with ***any*** lag time, let alone one that is pH sensitive:

> Q: Sure. ***But the specification doesn't provide any reason that a person of skill in the art would want a lag time, right?***
>
> A: ***No.*** That would be from the – the clinical development side of things.

[4] Consistent with the specification, Dr. Moreton agrees that that enteric pore formers are not the only way to introduce lag times into a formulation. A2208 at 141:25-142:9 (describing the use of a non-enteric coating that "slowly dissolves" to impart a lag time).

A2207 at 140:15-19. Dr. Moreton further conceded that the specification does not express any preference for when the release from the sustained release portion should occur:

> Q: Sure. Setting the lag time to one side, based on the specification of the '488 patent, do you understand there to be any limitations that are being placed on when the release from the controlled or sustained release formulation – could occur?
>
> A: Let me put it this way: Once the controlled release system is activated, whichever way, then it releases. But I don't think there's any – ***I don't recall anything in the patent which says that it has to be a lag time or not a lag time***.

A2188 at 63:13-25. Dr. Moreton also candidly acknowledged at his deposition that the specification does not express "a preference for the use of anything in particular as a pore former." Ex. 18 at 104:9-15. In fact, when asked about the description of the potential excipients in the functional coating (Ex. 1 at 11:54-13:57), which includes the reference to enteric pore formers, he acknowledged that the inventors were "listing different materials that can be used, ***no preference***." Ex. 18 at 106:5-6. Taken together, these undisputed facts demonstrate that there are no blaze marks in the specification that would direct a POSA to the claimed formulations.

Given the limited discussion of enteric compounds in the specification, Jazz's approach is particularly problematic. Jazz frames the question as whether the specification gives a POSA a reason to use MAMM co-polymers in the functional coating of a GHB formulation. Jazz Opp. Br. at 4, 7. Jazz answers "yes" to this question, because the specification discloses that "where a start-up lag time is desired, an enteric coating may be applied."[5] Ex. 1 at 18:60-62; Jazz Opp. Br. at 5. And because MAMM is one of three enteric compounds explicitly disclosed in the specification,

[5] This portion of the specification states that the enteric coating is applied "over the controlled release component (e.g., ***over a functional coating***)," Ex. 1 at 18:60-63, suggesting that it should not be included ***in*** the functional coating as claimed, making Jazz's reliance on it to provide adequate written description even more insufficient.

Jazz concludes that there are sufficient blaze marks and written description. Jazz Opp. Br. at 9-10. But the specification describes potential issues with enteric coatings too, and does not express any preference for them (or a lag time more generally):

> [S]uch a coating would necessarily limit the start-up lag to gastric residence and its associated variability. Use of enteric pore-formers would also impart a start-up lag, and such an embodiment would be more sensitive to food effects and gastric motility.

Ex. 1 at 18:63-67. Jazz's assertion that this limited disclosure would steer a POSA to the claimed subgenus of formulations fails as a matter of law.[6]

Jazz's cited cases do not suggest otherwise. As Jazz acknowledges, these cases involved patents whose specifications disclosed a much more limited number of choices for a POSA. *See, e.g.*, Jazz Opp. Br. at 9-10 (citing *Singh v. Brake*, 317 F.3d 1334, 1344 (Fed. Cir. 2003) and explaining that the claimed sub-genus corresponded to "one of five choices that had been described"). Jazz attempts to analogize its specification to the one at issue in *Singh*, but it does so only by presupposing (through impermissible hindsight) that a POSA would be looking specifically for disclosures about implementing a functional coating that provides a pH-sensitive lag time. Jazz then points to the three enteric compounds explicitly described in the specification. Jazz Opp. Br. at 10. But as confirmed by Dr. Moreton, the specification would not steer a POSA towards such formulations, particularly in the form of the claimed formulation as an integrated whole. *See* A2188 at 63:13-25; A2198 at 104:9-15; A2199 106:5-6; A2207 at 140:15-19.

[6] Jazz argues that experts dispute whether these disclosures teach away from the use of MAMM, and therefore summary judgment is inappropriate, Jazz Opp. Br. at 8-9, but Jazz misses the point. Whether or not those disclosures are sufficient to teach a POSA away from the use of MAMM (they are), there is no dispute that the specification does not express any preference for formulations with a lag time, let alone a pH-sensitive lag time accomplished by incorporating MAMM into the formulation. *See* A2207at 140:15-19.

The *Immunex* decision cited by Jazz also involved a narrow claim scope with clear blaze marks towards the claims. There, the claimed fusion protein was one of four preferred fusion proteins described in the specification. Jazz Opp. Br. at 10 (citing *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1065) (Fed. Cir. 2020)). Jazz notes that the specification of the SR patents does not disclose *any* preferred embodiments, just "particular" embodiments. Jazz Opp. Br. at 4, n.3. That is precisely why summary judgment is warranted. Jazz's specification lists out various excipients and describes various formulations (none of which include MAMM[7]), without steering a POSA toward ***any*** of them in particular. Instead, as Dr. Moreton confirmed, the specification just "list[s] different materials that can be used, no preference." Ex. 18 at 106:5-6. In view of Dr. Moreton's testimony and the express disclosures of the SR specification, there are no genuine factual disputes about whether the specification contains blaze marks sufficient for the claimed formulations overall. It does not, and summary judgment of invalidity for lack of written description is warranted. *See Boston Scientific Corp. v. Johnson Johnson*, 647 F.3d 1353, 1367 (Fed. Cir. 2011) (affirming District Court's grant of summary judgment of invalidity based on a lack of blaze marks); *see also Lipocine Inc. v. Clarus Therapeutics, Inc.*, 541 F.Supp. 3d 435, 468 (D. Del. 2021) (granting summary judgment of invalidity based on a lack of blaze marks).

[7] Jazz contends that Avadel's expert, Dr. Charman "agrees that 'one embodiment' described in the SR Specification is a sustained release formulation with a functional coating comprised of the claimed MAMM co-polymers." Jazz Opp. Br. at 4 (citing CoF No. 8). Not so. Dr. Charman was asked whether "the inventors are saying, here's one embodiment of my invention, the methacrylic acid-methylacrylate copolymers as enteric coatings or enteric pore formers," and he agreed that is disclosed. *See* A1524, 359:17-22. The preceding questions make it clear that "embodiment" was a reference to enteric compounds as "one embodiment of the pore formers", not an embodiment of a sustained release formulation. *Id.* at 356:22-357:25.

C. The SR Specification Does Not Disclose Common Structural Features of Formulations That Will Exhibit the Claimed Dissolution Profiles

Jazz does not dispute that the specification fails to describe any specific formulations that embody the compositional requirements of the claims (i.e., containing MAMM). Jazz notes that the formulation disclosed in Example 2 of the specification tracks the claimed release profile, i.e., the functional requirements of the claim (Jazz Opp. Br. at 6), but that is a strawman—the formulation of Example 2 is not an embodiment of any claim because it does not include any MAMM; it uses hydroxypropyl cellulose, a non-enteric/non-pH sensitive pore former. Jazz points to no disclosure in the specification that using MAMM instead would result in the claimed release profile. Nor could it. The words of the specification reciting MAMM are entirely unremarkable: "Examples of such materials that may be used as a pore former in the context of the present description include cellulose acetate phthalate, methacrylic acid-methyl methacrylate copolymers, and polyvinyl acetate phthalate." Ex. 1 at 13:28-32. That is the entirety of the disclosure specific to MAMM, which fails to draw any specific attention to it, or note any structural features specific to it that would result in the release profile for the claimed sub-genus of formulations.

Jazz nonetheless contends that the "SR Specification describes in detail the structural elements of the functional coating that are relevant to facilitating the desired release profile." Jazz Opp. Br. at 13. But Jazz cites to no portion of the specification to support this assertion, and the specification's general disclosure that enteric pore formers can be used to provide a pH-sensitive lag time does not address what release profile MAMM will provide in any given formulation. Thus, a POSA would be unable to discern which MAMM-containing formulations that satisfy the structural/compositional requirements of the claims will also exhibit the claimed release profile.

The *Nalpropion* decision cited by Jazz is irrelevant. It pertains to whether one test methodology is "substantially equivalent" to another for written description purposes, not whether

the specification discloses structural features common to a claimed genus. *Nalproprion Pharms., Inc. v. Actavis Labs. FL, Inc.*, 934 F.3d 1344, 1350 (Fed. Cir. 2019). The decision does not address whether the specification discloses structural features common to members of a genus sufficient for a POSA to identify members of the genus that will also satisfy functional requirements of the claim. *Biovertiv Inc. v. CSL Behring LLC*, No. 17-914, 2020 WL 1066019 (D. Del. Mar. 5, 2020). It is also inapposite, because there, the parties disputed the scope of the genus described in the claims and whether a skilled artisan could envision the claimed genus "with reference to its structural features alone." Jazz Opp. Br. at 12. Here, the plain language of the claims prevents any material dispute on the scope of the genus. The claims cover formulations with varying amounts of GHB, varying amounts of MAMM, and varying amounts of the numerous other excipients contemplated by the specification. Jazz has not identified any structural features common to formulations satisfying the claimed compositional requirements that will also exhibit the claimed release profile.

Jazz attempts to distinguish the *Allergan USA* and *Idenix Pharmaceuticals* decisions cited by Avadel on the grounds that they dealt with claims to much broader genera than are at issue here. Jazz Opp. Br. at 13-14. But when the specification is considered as a whole, it is clear that it describes a large genus of potential formulations. What is unclear and warrants summary judgment, is which members of that genus will also have the claimed release profile. *Id.* at 12-14.

Judge Bryson's decision in *Lipocine v. Clarus Therapeutics* is directly on point. Jazz characterizes the decision as being one about "purely functional terms," Jazz Opp. Br. at 14, but that is not accurate. The claims at issue in *Lipocine* were "largely defined by functional limitations," but "contain[ed] minimal formulation restrictions," such as the amount of testosterone undecanoate being dosed in the claimed regimen, and certain categories of excipients. *Lipocine*

Inc. v. Clarus Therpaeutics, 541 F. Supp.3d 435, 439 (D. Del. 2021). While the claims of the SR patents may include slightly more structural limitations than those at issue in *Lipocine*, the claims here are still quite broad in terms of the compositions they cover.[8] And they suffer from the same problem that was fatal to the claims in *Lipocine*—"there is no basis from which to conclude that the functional limitations" of the claims will be satisfied. 541 F. Supp. 3d at 467. In *Lipocine*, there were at least *some* formulations disclosed that satisfied the structural and functional requirements of the claims. Here, there are none. Pltfs.' Resp. to SMF ¶ A-11. Accordingly, summary judgment for lack of written description is warranted for this additional reason as well.

II. AVADEL'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT NO. 2 – INVALIDITY OF ASSERTED CLAIMS OF THE '079 AND '782 PATENTS FOR LACK OF ENABLEMENT

Jazz fails to raise any material dispute with respect to the two underlying issues that put this case squarely within the ambit of *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023) and *Baxalta Inc., v. Genentech*, 81 F.4th 1362 (Fed. Cir. 2023): (1) the claims at issue are directed to a broad functional genus of oxybate formulations; and (2) the specification does not identify a quality common to every functional embodiment that would allow a POSA to predict which formulations will control drug release and avoid engaging in rote trial-and-error to practice the full scope of the claims. *See Baxalta*, 81 F.4th at 1366-67; *Amgen*, 598 U.S. at 613-15. Jazz disagrees that the claims are broad, but tellingly fails to identify any limitation to the scope of the claims. Jazz also contends that the teachings in the specification would allow a POSA to avoid the type of rote experimentation that doomed the patents at issue in *Baxalta* and *Amgen*, but those assertions fail as a matter of law.

[8] For example, Jazz characterizes the claimed "core" as a structural requirement of the formulation. Jazz Opp. Br. at 14. As Avadel previously explained, the specification describes numerous excipients that can be included in this part of the claimed formulation. Br. at 5-6.

First, Jazz's opposition simply echoes the vague, unsupported assertions by its expert of the specification's alleged teachings without ever citing any specific disclosures in the specification. ***Second***, Jazz's experts fail to identify any "quality common to every functional embodiment" (*Amgen*, 598 U.S. at 614), that would allow a POSA to predict which formulations of oxybate will control or modify release. In the absence of any genuine material dispute regarding the teachings of the specification, summary judgment for lack of enablement is warranted.

A. The Claims Are Directed to a Broad Functional Genus

Jazz does not dispute that the asserted claims recite sodium oxybate formulations defined by their functional ability to control or modify the release of sodium oxybate. Br. at 19. Instead, Jazz asserts that the universe of materials that can be used to control release is limited in some way, either by the purpose of the invention (Jazz Opp. Br. at 6), by what Jazz labels as "structural" features of the claims (*id.*), or because a POSA allegedly would not view the claims as encompassing the hundreds of thousands of formulations that can be made by combining materials the applicants recited as appropriate for controlling release of oxybate. *Id.* at 7. Absent from Jazz's opposition is any explanation of exactly ***how*** the scope of the claims are limited.

Avadel pointed out that the '079 and '782 patent specification—through the incorporation by reference of Allphin 2012—includes a long list of materials that purportedly can be used to control release of oxybate. Br. at 19-20. Jazz responds by pointing to Dr. Little's belief that the claims' recitation of a sachet (the '079 patent) and a viscosity enhancing agent and an acid (the '782 patent) are "structural requirements" that limit the other types of materials that could be used (Jazz Opp. Br. at 6). But Dr. Little provides no explanation for this belief, which is unsupported by any citation to the specification or reference to knowledge in the art. *See* CoF No. 5 (Dr. Little asserting that the "theoretical universe of materials that could be used to control drug release is cabined by the claims" without providing any explanation of how, specifically, the materials are

cabined). Such unsupported *ipse dixit* by a party's expert cannot create a material issue of fact. *InterDigital Commc'ns, Inc. v. ZTE Corp.*, No. 1:13-CV-00009-RGA, 2014 WL 4272726, at *3 (D. Del. Aug. 28, 2014), aff'd, 711 F. App'x 998 (Fed. Cir. 2017) (granting summary judgment where the expert cited no evidence of the amount of experimentation needed).

Jazz's contention that the claims are directed to "administrability" rather than controlling the release of oxybate is immaterial. Jazz Opp. Br. at 4, 6. Regardless of whether the "crux" of the invention is administrability,[9] the relevant point is that the asserted claims cover a broad genus of formulations having a "controlled release component" or "modified release particles." Jazz never explains how the purported goal of improving administrability limits the possible types of formulations covered by Jazz's broad claims.

Jazz's disagreement with Avadel's explanation for why hundreds of thousands of non-resinate formulations are covered by the claims (Jazz Opp. Br. at 7) is similarly unfounded. Jazz relies on Dr. Little's conclusory assertion that a POSA would simply ignore vast numbers of formulations resulting from combinations of the materials listed in the specification (*id.*), but that approach is clear error. Federal Circuit authority makes clear that the appropriate analysis requires first determining the scope of claims and then analyzing whether the specification provides enough guidance to allow a POSA to avoid engaging in rote trial and error experimentation to practice the full scope of the claims. *See Baxalta*, 81 F.4th at 1365-66. Jazz's refusal to engage in any analysis of the breadth of the claims is simply at odds with controlling case law. It is also factually wrong: Dr. Little admitted that the number of formulations potentially falling within the scope of the claims was "infinity." SMF ¶ B-12. That corroborates Dr. Charman's unrebutted opinion that the scope of the claims at issue is extensive. Br. at 19 (citing SMF ¶ B-9).

[9] No claim limitation supports Jazz's assertion.

Worse, Jazz never provides any counter-calculation demonstrating what the full scope of the claims would be under its view—let alone create a genuine dispute that the claims encompass tens of thousands of formulations. Dr. Little's conclusory assertion that "there's guidance and categories of different excipients and different things" in the specification and a formulator "realize[s] that each of these is a category of being able to tune," Jazz Opp. Br. at 7, is insufficient to raise any material disputes about the broad scope of the claims. *See TechSearch, LLC. v. Intel Corp.*, 286 F.3d 1360, 1372 (Fed. Cir. 2002) ("[G]eneral assertions of facts, general denials, and conclusory statements are insufficient to shoulder the non-movant's burden.") (citations omitted).

B. Extensive Trial and Error Is Required to Practice the Full Scope of the Claims

Jazz also fails to raise any genuine dispute that practicing the full scope of the claims requires extensive trial and error. The specification lacks any "disclosure[]—such as 'a quality common to every functional embodiment,' *Amgen*, 598 U.S. at 614—that would allow a skilled artisan to predict which [formulations] will perform the claimed functions." *Baxalta*, 81 F.4th at 1366; Br. at 21-22. Instead, the specification (via incorporation of Allphin 2012),[10] merely provides a laundry list of materials that can be used in a controlled-release formulation and a mechanism to test whether the formulation controls the release of oxybate.

Jazz identifies no teachings in the specification of the '079 and '782 patent itself, or Allphin 2012, that would avoid, or even limit, the need for trial and error. Jazz's opposition brief cites the specification of the patents only twice: first at 5:37-6:11 (Jazz Opp. Br. at 5), which lists the difficulties with formulating oxybate, and next at 13:57-14:30 (*id.*), which list excipients like colorants, flavoring agents, stabilizing agents, and pH adjusting/buffering agents which may be

[10] Contrary to Jazz's suggestion, Avadel does not dispute that Allphin 2012 is incorporated by reference into the specification of the '079 and '782 patents for the purposes of this motion.

used in a formulation. These disclosures do not instruct a POSA how to combine materials into a formulation to control release of oxybate, nor do they allow a POSA to "predict which [formulations] will perform the claimed functions." *Baxalta*, 81 F.4th at 1366.

Jazz attempts to manufacture a dispute primarily by once again relying on Dr. Little's vague recitations of what the patents teach. Those efforts fail, as the cited testimony is conclusory and immaterial. Initially, Jazz cites Dr. Little for the notion that he has never "seen a patent go through all of the things that wouldn't work," and that Allphin 2012 "focuses on formulations that would provide the desired behavior." (Jazz Opp. Br. at 11-12). But that simply identifies a desired function, not any guidance for making the full scope of the claimed compositions, or a teaching that would enable a POSA to predict which formulations will work as claimed without rote trial and error. *Baxalta*, 81 F.4th at 1366. Jazz similarly does not point to any specific teachings in Allphin 2012 that would tell a POSA how to select and combine materials to control release of oxybate or predict which of the vast array of non-resinate formulations will do so. Even if the specification would lead a POSA to test some materials that allegedly might work, enablement requires disclosures that "reliably enable a person skilled in the art to make and use ***all*** of what is claimed, ***not merely a subset***." *Amgen*, 598 U.S. at 611.

Jazz provides no meaningful response to acknowledgement in the specification that Allphin 2012 does not provide sufficient instruction to a POSA on how to control release of oxybate using "conventional" non-resinate techniques. The patent is clear and unambiguous: the properties of GHB "complicate, and in many cases, ***limit*** conventional approaches for modified release" and "***significantly reduce*** the number of viable approaches using such conventional solubility and diffusivity control technologies." Ex. 5 at 5:54-60. Dr. Little conceded that the latter means exactly what it says, and that the specification provides zero guidance to a POSA as to which

techniques will work. Br. at 26 (citing SMF ¶ B-34). Thus, the specification's characterization of Allphin 2012 reflects the status of non-resinate controlled release oxybate formulation at the time of the invention: that a POSA would not know how to make and use their full scope without trial and error.[11]

Jazz's attempt to dispute Avadel's observation that Dr. Little relies exclusively on Allphin 2012 for a substantive disclosure of non-resinate controlled release formulations also fails. Jazz argues that there is "support" for non-resinate formulations in the text of the '079 and '782 patents. Jazz Opp. Br. at 10. But the alleged support Jazz points to are generic recitations of desired outcomes, not specific teachings of how to use non-resinate materials to control release of oxybate. Statements like "the present invention provides a GHB formulation which delivers a controlled release profile, for example a controlled release profile suitable for once-a-day dosing" or "one embodiment of the invention is a GHB formulation comprising polymeric beads and pharmaceuticals" (CoF No. 19), provide no information on how to actually make such formulations.

Finally, Jazz cannot overcome the lack of enabling disclosure by arguing that any experimentation required is routine. Jazz Opp. Br. at 8-9. Even routine experimentation is undue where the only instruction on how to practice the full scope of the claims is to make and test tens of thousands of formulations. *See Baxalta*, 81 F.4th at 1365 (holding that the "routine screening" described in the patent constitutes undue experimentation). To the extent the pre-*Amgen* cases Jazz cites (Jazz Opp. Br. at 8-9) impose a looser enablement standard than *Amgen* and *Baxalta*, those cases no longer control. As the Federal Circuit recently explained, "[u]nder *Amgen*, such

[11] To be clear, Avadel did not argue that a POSA would "disregard" the disclosure of Allphin 2012 (Jazz Opp. Br. at 11), just that it is not sufficient to enable the full scope of the claims.

random trial-and-error discovery, without more, constitutes unreasonable experimentation that falls outside the bounds required by § 112(a)" as a matter of law. *Baxalta*, 81 F.4th at 1367.

Jazz's attempt to rely on *Janssen* and *Orexo* to distance itself from *Amgen* and *Baxalta* fails. Jazz Opp. Br. at 8, 14. Both are distinguishable from the facts of this case and highlight the shortcomings of Jazz's specification. In *Janssen*, the defendants argued that the claims were broad based on the variety of potential inactive ingredients that merely "help provide the collected dosage form" of the claimed formulation. *Janssen Pharm., Inc. v. Mylan Laby's Ltd.*, No. 20-13103, 2023 WL 3605733 at *35 (D.N.J May 23, 2023). The Court found that a POSA "would be familiar with the classes of excipients" and "***what they do as well as the amount that you would use***." *Id*. Here, the breadth of the formulations is due to the ingredients that could be used to control release, ***a feature required by the claims***. And there is no evidence (beyond Dr. Little's unsupported say-so) that a POSA would know how to use these ingredients to control oxybate release.

Moreover, the Court's decision in *Janssen* was rooted in a finding that although the claims did "not specify the particle size or excipients (and their concentration)," the patent contained "ample information in the specification about all the structural features" of the compound at issue and a "recipe to make" it such that a POSA could make the claimed formulation "without the necessity for experimentation." *Id*. at *34, *36. Here, in contrast, Jazz has not pointed to a "recipe" to make and use the full scope of the claimed formulations, and there is no dispute that a POSA would have to make and test each potential member of the genus to determine whether it performs the functional requisite of the claims. SMF ¶ B-31. Indeed, Jazz effectively admits that the specification does not provide a recipe negating the need for experimentation by relying on a contention that such rote "experimental work would be 'common' formulation work for a POSA." Jazz Opp. Br. at 8.

Orexo is similarly distinguishable. The patent in *Orexo* was directed to "a single composition of an opioid dependence drug." *Orexo AB v. Sun Pharmaceuticals Ltd*., No. 3:20-cv-12588, 2023 WL 4492095 at *24 (D.N.J. Jun. 30, 2023). Jazz alleges that *Orexo* rejects the Amgen-based enablement defense because the patent at issue covered "a narrow composition covering a sublingual tablet" rather than an entire genus. Jazz Opp. Br. at 14. But there was nothing in the claims at issue *Orexo* defining the claimed composition by its function. *Orexo* at *24. Accordingly, *Orexo* is inapplicable here. Jazz does not dispute that the asserted claims recite a functional genus formulations defined by their ability to control release of oxybate. Thus, like the functional claims in *Amgen*, the controlled/modified release formulations claimed in the '079 and '782 patents cover a broad, functional genus of formulations.

The additional "disputes" Jazz injects with respect to the remaining *Wands* factors are immaterial. As an initial matter, Jazz is incorrect that courts "must" address the Wands factors to decide enablement (Jazz Opp. Br. at 2). *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc*., 665 F.3d 1269, 1288 (Fed. Cir. 2012) (The *Wands* factors "are illustrative, not mandatory."); *see also Baxalta*, 81 F.4th at 1367. In any event, Avadel did address the pertinent *Wands* factors—Jazz's arguments about the *Wands* respond to corresponding arguments Avadel made in its opening brief. *See* Resp. §III.B.; Jazz Opp. Br. §IV.B.

The purported factual disputes identified by Jazz do not change the lack of enablement conclusion of non-enablement that flows from *Baxalta* and *Amgen*. Jazz cannot reasonably deny that the patents and its expert acknowledge that oxybate is difficult to work with. *See* SoF B-2 (Dr. Little agreeing that "formulation science is complex and often unpredictable" and that "oxybate is a difficult drug to work with."); Ex. 5 at 5:49-60 (listing the characteristics of oxybate that "complicate" conventional approaches to modifying its release). Likewise, there are no

working examples in Jazz's patents that embody the claims (i.e., describing particle formulations that include a sachet, a viscosity enhancing agent, and/or an acid). Moreover, Allphin 2012 at best offers an example of one set of ingredients in varying proportions for use in a functional coating for a tablet (not particles, as claimed). Jazz cannot credibly assert that this provides an enabling disclosure of the full scope of the claims, just as the eleven candidate antibodies taught in the specification of the *Baxalta* patent were not sufficient to support enablement. *Baxalta*, 81 F.4th at 1364. In sum, *Amgen* and *Baxalta* apply here. Practicing the claims requires a POSA to engage in random, extensive trial and error. Summary judgment for lack of enablement is therefore appropriate.

III. AVADEL'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE THE TESTIMONY OF MARK RAINEY, PH.D[12]

Jazz's opposition fails to justify Dr. Rainey's challenged opinion. Avadel's motion did not contend that Dr. Rainey skipped any *Georgia-Pacific* factors as Jazz suggests, nor does Dr. Rainey's invocation of those factors immunize all his opinions from legal challenge. Rather, Dr. Rainey stepped outside the law in opining that Avadel [redacted] necessary to keep Jazz from excluding LUMRYZ from the market, [redacted] at the hypothetical negotiation if its demands were not met. [redacted] That does not represent a negotiation between a willing licensor and licensee as the law requires, and Jazz cannot pretend otherwise simply because the word "negotiation" appears in Dr. Rainey's report. Dr. Rainey's failure to meaningfully treat Jazz as a willing licensor should result in the exclusion of his tainted opinions.

[12] In view of the Court's Memorandum Opinion regarding claim construction (D.I. 419), Avadel withdrew its Motion for Summary Judgment No. 3 (*see* D.I. 458).

A. Additional Factual Background

Dr. Rainey expressly opined that Avadel would be [redacted] which would happen if Avadel did not agree to Jazz's demands (emphases added throughout):

[redacted]

Ex. 15 ¶ 165. Dr. Rainey's Reply report further demonstrates that Dr. Rainey did not consider Jazz to be a willing licensor. As Dr. Rainey stated in describing his opening report, [redacted] A2809 at ¶ 17. Dr. Rainey then re-confirmed that in his version of the hypothetical negotiation, [redacted] A2843 at ¶ 98.

B. Argument

Federal Circuit precedent is clear: "The notion that license fees that are tainted by the coercive environment of patent litigation are unsuitable to prove a reasonable royalty is a logical

extension of *Georgia–Pacific*, the premise of which 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). Jazz contends that *LaserDynamics* has different facts, but that does not change its holding—[redacted] do not fit the hypothetical negotiation.

Dr. Rainey's opinions improperly rely on [redacted] and patent litigation and so should be excluded. Avadel concedes that Dr. Rainey's [redacted] is not predicated on a settlement agreement, but his analysis is predicated on [redacted] In his view, Jazz gets everything it wants at the hypothetical negotiation, [redacted] His view that Avadel would be willing to pay whatever Jazz demands [redacted] which is not a part of the hypothetical negotiation. *Cf. id.* at 78 ("The BenQ settlement agreement was executed shortly before a trial—a trial in which BenQ would have been at a severe legal and procedural disadvantage . . . . The $6 million lump sum license fee is six times larger than the next highest amount paid for a license to the patent-in-suit, ***and ostensibly reflects not the value of the claimed invention but the strong desire to avoid further litigation under the circumstances***"). That Dr. Rainey also offered other opinions—Jazz's main defense in its opposition—does not change [redacted] Avadel's motion does not seek to take away from the jury any issue of fact, as Jazz argues. It seeks to exclude analysis that is contrary to law.

None of Jazz's cases are to the contrary. Many do no more than state basic principles. *See, e.g., Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1303–04 (Fed. Cir. 2015) (explaining that the reasonable royalty analysis "posits a 'hypothetical negotiation' between a 'willing licensor' and a 'willing licensee' to ascertain the royalty upon which the parties would

have agreed had they successfully negotiated an agreement just before infringement began" (quotation omitted)). Others involved entirely different challenges to expert opinions. In *Summit 6*, involving cell phone cameras, the expert's analysis was attacked based on issues such as his use of survey evidence. *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1297 (Fed. Cir. 2015). [redacted] in *TRUSTID* or *MicroChem. See TRUSTID, Inc. v. Next Caller Inc.*, No. CV 18-172 (MN), 2020 WL 5016924, at *3 (D. Del. Apr. 21, 2020) (discussing reliance on reseller agreements rather than comparable licensing agreements); *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1394 (Fed. Cir. 2003) (considering whether an expert properly ignored a non-infringing alternative).

In *Asetek*, after noting that profits may be considered in the reasonable royalty analysis, the Federal Circuit reaffirmed that the reasonable royalty analysis is between willing parties without the patentee dictating terms: "A hypothetical-negotiation analysis for a royalty considers not only the patent owner's interests, ***but also the other side of the negotiation table under the particular conditions of the hypothetical negotiation***. A lost-profits analysis is different, because as a general matter, the patent owner is entitled to be made whole, upon proper proof, for its loss of profits caused by the infringement, ***without discounting for the rational interests limiting willingness to pay on the infringer's side***." *Asetek Danmark A/S v. CMI USA Inc.*, 852 F.3d 1352, 1363 (Fed. Cir. 2017) (emphasis added) (citation omitted). Dr. Rainey concededly did not conduct a proper "but-for" lost profits analysis, (Ex. 15 ¶ 29, fn. 20), [redacted]

In sum, the law requires Dr. Rainey to treat Jazz as a willing licensor, and he did not do so.

[redacted] If, at

trial, Dr. Rainey repeats his argument that Avadel would agre [redacted] Avadel expects, however, that Dr. Rainey will not offer that justification in support of [redacted] Jazz has not shown that [redacted] must rise or fall together.

IV. AVADEL'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE THE TESTIMONY OF CHRISTIAN MORETON, PH.D

Jazz opposes Avadel's motion to exclude expert testimony from Dr. Moreton by pointing to various instances in which Dr. Moreton opined that he relied on the specification as part of the written description analysis. Opp. at 2-3. That is true, and Avadel never argued otherwise. The problem though, which warrants exclusion of Dr. Moreton's testimony, is that he clearly stated in his expert report that he was also relying on the claims themselves to provide written description support. Br. at 35-36. Jazz accuses Avadel of cherry-picking sentences out of Dr. Moreton's report (Opp. at 2), but Avadel has done no such thing. Avadel simply took Dr. Moreton's opinions at face value and moved to exclude them because they are improper. The fact that Dr. Moreton may have relied on the claims ***and*** the specification for written description support (Opp. at 2-3, citing A2252, ¶ 44) does not change the fact that it is legally improper to rely on the claims in this fashion at all. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1329 (Fed. Cir. 2000). Dr. Moreton's written description opinions should therefore be excluded, or at a minimum, he should be precluded from relying on the issued claims themselves for written description support.

V. AVADEL'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE THE TESTIMONY OF STEVEN LITTLE, PH.D.

Jazz fails to address the core of the dispute: "Dr. Little should not be able to testify to the jury that the non-resinate embodiments of the asserted claims are enabled." Opening Br. at 41. Instead, Jazz cites dozens of paragraphs from Dr. Little's expert report that either do not pertain to

non-resinate embodiments or do not pertain to enablement. Jazz's effort to cobble together disparate portions of Dr. Little's report further highlights Dr. Little's failure to perform an appropriate enablement analysis for non-resinate aspects of the asserted patents.

A. The Additional Portions of Dr. Little's Opinions That Jazz Identified Do Not Address Enablement of Non-Resinate Embodiments

Jazz argues that "Dr. Little's report demonstrates a detailed analysis of the challenged non-resinate enablement issue" (Opp. at 1), but Jazz's citations show otherwise. Jazz cites to various paragraphs in both Dr. Little and Dr. Moreton's expert reports, which it breaks down into five categories: (1) a "summary of enablement opinions"; (2) a "discussion of non-resinate controlled/modified release disclosures in the '079/'782 Patents"; (3) "enablement opinions specific to non-resinate controlled/modified release"; (4) "*Wands* factors analyses"; and (5) "portions of Dr. Christian Moreton's report which Dr. Little agrees with and relies upon." *Id.* Only category three contains "enablement opinions specific to non-resinate controlled/modified release," and tellingly Jazz only identifies two paragraph that fall in that category. The remaining four categories do not provide any substantive enablement analysis of non-resinate embodiments.

Category one is just a general summary of Dr. Little's enablement opinions. Opp. at 1 (citing A2500, ¶ 4, A2532-A2533, ¶ 71, A2563, ¶ 143). It does not include any substantive analysis, but merely contains conclusory statements that the '079/'782 patents are not invalid.

Category two relates to "non-resinate controlled/modified release disclosures." Opp. at 1 (citing A2506-A2517, ¶¶ 21-42, A2548-A2558, ¶¶ 115-131). Jazz does not argue that the cited paragraphs concern enablement and with good reason; they are from Dr. Little's ***written description*** opinion. *Id.* Jazz cannot rely on Dr. Little and Dr. Moreton's written description opinions to substitute for enablement because the relevant facts and methodology are different. While Jazz asserts that enablement and written description "are often met by the same disclosure,"

(Opp. at 3 n.4), the Federal Circuit in *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.* recognized "the existence of a written description requirement separate from enablement," and that difference is relevant here. 598 F.3d 1336. 1340 (Fed. Cir. 2010) (*en banc*). As Jazz acknowledges, it is an "unremarkable principle that 'enabling disclosure of the *novel* aspects of the invention [must] come from the specification." Opp. at 5 (alterations in original). Dr. Moreton's written description analysis—and Dr. Little's review of it—rely heavily on Allphin 2012, a prior art publication that was incorporated by reference into the '079/'782 patents. A2511 at ¶ 30. Yet that prior art cannot support an enabling disclosure for an invention's novel aspects. Nowhere in his enablement opinions does Dr. Little consider how the use of a prior art disclosure would impact his opinions, let alone whether the non-resinate embodiments are enabled without that prior art disclosure.

Category four Jazz labeled as "*Wands* factors analyses." Opp. at 1 (citing A2540-A2546, ¶¶ 90-102, A2565, ¶¶ 149-152). None of the 24 paragraphs that Jazz identified actually apply the *Wands* factors to the ***non-resinate*** aspects of the claims.

Finally, category five does not even contain Dr. Little's opinions. Rather, those paragraphs are "portions of Dr. Christian Moreton's report," which Jazz asserts "Dr. Little agrees with and relies upon." Opp. at 1 (citing A2251-A2262, ¶¶ 42-62, A2267-A2270, ¶¶ 73-80, A2273-A2278, ¶¶ 88-94). But Dr. Little does not even mention Dr. Moreton's report in the context of enablement. Rather, Dr. Little explains that he reviewed and considered it in the context of written description. Ex. 10, Little Rebuttal Rpt. at ¶ 79. Dr. Little provides no explanation for how his review of Dr. Moreton's analysis would translate to enablement.

B. Dr. Little's Cursory Opinions on Enablement Do Not Set Forth Facts And Methodology

Dr. Little's limited opinions that actually address the enablement of non-resinate embodiments are cursory and insufficient, as Dr. Little failed to set forth the facts and methodology

he relied on. Category three consists of a single paragraph for each patent. As explained in Avadel's opening brief, these paragraphs are primarily dedicated to recounting Dr. Charman's opinions before the inclusion of a conclusory assertion that the "written description would teach a POSA how to make and use the claimed inventions, including non-resinate controlled release components." Opening Br. at 38-39 (citing Ex. 10, Little Rebuttal Rpt. ¶ 79); *see also* A2563, ¶ 145 (addressing the '782 patent). Such "conclusory opinions" are appropriately excluded from the jury. *Adasa Inc. v. Avery Dennison Corp.*, 55 F.4th 900, 915 (Fed. Cir. 2022).[13]

Jazz cannot rely on Dr. Little's written description opinions either, because they are based on a prior art disclosure that Jazz agrees cannot support an enabling disclosure for an invention's novel aspects. *See supra* at § V.A. Jazz asserts that this is of no concern, because "it is Dr. Little's opinion that, by the time of the '079/'782 Patents, formulating non-resinate controlled/modified release oxybate was known; what is novel is the administrability through the use of the claimed sachet (for the '079 Patent) and the claimed viscosity enhancing agent and acid separate from the oxybate particles (for the '782 Patent)." Opp. at 5 (citing A0621 5:37-6:11; A0625, 13:57-14:30; A2508, ¶ 24; A2509, ¶ 26; A2513-A2514, ¶¶ 34-35; A2548, ¶ 115; A2550-A2551, ¶ 118). But these citations do not actually support Jazz's argument. Nowhere in them does Dr. Little opine that "by the time of the '079/'782 Patents, formulating non-resinate controlled/modified release oxybate was known," nor does he describe any proper analysis of the alleged enablement of the allegedly novel subject matter. Dr. Little failed to conduct the proper analysis, and his enablement opinion regarding non-resinate embodiments accordingly should be excluded.

[13] In a footnote, Jazz argues that *Adasa* "does not relate to the substance or depth of Dr. Little's opinions at all." Br. at 4-5 n.6. But, as in *Adasa*, Dr. Little has failed to undertake any meaningful analysis.

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