IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW

MEMORANDUM OPINION

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Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

In these actions filed by Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz") against Defendant Avadel CNS Pharmaceuticals, LLC ("Avadel"), Jazz alleges infringement of U.S. Patent Nos. 8,731,963 ("the '963 patent"), 10,758,488 ("the '488 patent"), 10,813,885 ("the '885 patent"), 10,959,956 ("the '956 patent"), 10,966,931 ("the '931 patent"), 11,077,079 ("the '079 patent"), and 11,147,782 ("the '782 patent").[1] Before the Court is the issue of claim construction of multiple terms in these patents. The Court has considered the parties' joint claim construction brief and the accompanying appendix. C.A. No. 21-691, D.I. 132 & 133-1. The Court held a claim construction hearing on October 25, 2022 (the "Hearing").

I. LEGAL STANDARDS

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) ("A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention"). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* The ultimate question of the proper construction of a patent is a question of law, although

[1] Docket numbers identified herein refer to C.A. No. 21-691-GBW unless otherwise noted. The Court writes for the benefit of the parties and assumes their familiarity with these actions.

subsidiary fact-finding is sometimes necessary. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996)).

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1312–13). A person of ordinary skill in the art "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at at 1313.

"When construing claim terms, the court first looks to, and primarily rely on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). "Other claims of the patent in question, both asserted and unasserted, can . . . be valuable" in discerning the meaning of a disputed claim term because "claim terms are normally used consistently throughout the patent," and so, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314. In addition, "[d]ifferences among claims can also be a useful guide[.]" *Id.* For example, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition to the claim, the Court should analyze the specification, which "is always highly relevant to the claim construction analysis ... [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the

patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)). And, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The Court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution[.]" *Phillips*, 415 F.3d at 1317.

In some cases, the Court "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (internal quotation marks and citations omitted).

II. AGREED-UPON TERMS

The parties agreed upon the construction of claim term "by about 4 to about 6 hours" in the '488, '885, '956 and '931 patents to have its plain and ordinary meaning, which is "at any point prior to approximately 4 hours or at any point prior to approximately 6 hours". D.I. 145 at 3. The Court will adopt the agreed-upon construction.

III. DISPUTED TERMS

1. "sustained release portion"[2]

Disputed Term	Plaintiff Jazz's Construction	Defendant Avadel's Construction	The Court's Construction
"sustained release portion" ('488 patent; '885 patent; '956 patent; '931 patent)	Plain and ordinary meaning, i.e., the portion of the formulation that is not immediate release and that releases over a period of time	A gradual, extended release, as opposed to releasing a majority of the drug within an hour upon exposure to intestinal pH	Plain and ordinary meaning, i.e., the portion of the formulation that is not immediate release and that releases over a period of time

Jazz argues that Avadel's construction impermissibly imports time-dependent ("gradual, extended release") and pH-dependent ("as opposed to releasing a majority of the drug within an hour upon exposure to intestinal pH") limitations not supported by the intrinsic record. Avadel argues that Jazz clearly and unmistakably surrendered claim scope during prosecution.

Use of the disputed term in claim 1 of the '488 patent is representative:

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[2] Although the parties originally disputed whether the Court should construe the term "sustained release portion" (as advocated by Jazz) or "sustained release" (as advocated by Avadel), the parties maintain that their respective positions are correct regardless of which phrase the Court construes. D.I. 132 at 6 n.3; 10 n. 7. At the Hearing, Avadel confirmed that "there is no material difference as to whether you include 'portion' or simply construe 'sustained release.'" Tr. 17:4-10. The Court will construe the term "sustained release portion" in its entirety as the appropriate construction considers the entire phrase contextually in light of the intrinsic record.

> 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 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 . . . .

'488 patent at cl. 1. Starting with the claims, they require that the formulation comprise both "immediate release and sustained release portions." *Id.* Thus, on their face, the claims distinguish between immediate and sustained release, suggesting that the Court should construe "sustained release portion" in a manner that distinguishes it from the immediate release portion. While Avadel proposes that the Court construe "sustained release" to include specific time-dependent ("gradual, extended release") and pH-dependent ("as opposed to releasing a majority of the drug within an hour upon exposure to intestinal pH") drug release characteristics, the claims set forth the specific dissolution profile and the specific media used—that is, the "sustained release portion" of the claimed formulation must "release[] greater than about 40% of its gamma-hydroxybutyrate by about 4 to about 6 hours when tested in a dissolution apparatus 2 in deionized water . . . ." Thus, the claim language recites a dissolution profile measured in deionized water using expressly identified time limits.

Turning to the specification, it repeatedly refers to the invention as releasing over "a prolonged period of time." *See, e.g.*, '488 patent at 16:12-13. While Avadel argues that these disclosures undermine the "any" time period implicit in Jazz's proposed construction, Jazz's construction is not unbounded—rather, the relevant time period is expressly set forth in the claims. The specification is also consistent with the claimed dissolution profile measured in deionized water. *See* '488 patent at 7:64-8:1 ("Drug 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."). While the '488 patent's specification provides examples of other dissolution media that could be employed in certain embodiments (e.g., "simulated intestinal fluid," '488 patent at 8:4), that media was not recited in the claims, undermining Avadel's effort to include a limitation based on the sustained release portion's exposure to intestinal pH.

Avadel seeks to exclude the pH-based intestinal release profile from the scope of the claims by arguing that Jazz clearly and unambiguously surrendered claim scope during prosecution. "Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution." *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006). Prosecution disclaimer can arise from both claim amendments and arguments made to the PTO. *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013). The doctrine does not apply unless the disclaimer is "both clear and unmistakable to one of ordinary skill in the art." *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007) (quotations omitted).

The originally-filed claims did not contain the "sustained release" limitation. Instead, they were directed to "controlled release" portions. D.I. 133-1 at Ex. A. The examiner rejected those

claims as obvious over prior art that disclosed a "controlled release." D.I. 133-1 at Ex. B. Jazz amended the claims to replace "controlled release" with "sustained release" (D.I. 133-1 at Ex. A at 2-5), and later distinguished "sustained release" from the prior art by arguing that "sustained release" formulations "provide for a more gradual, but extended release" while the prior art's "delayed release" formulations "quickly release the majority of the drug." Ex. 133-1 at Ex. B. A declaration submitted by a named inventor states that, "[o]ur aim was to develop GHB formulations that . . . proved (sic) sustained release throughout the ileum and jejunum, rather than [the prior art's] delayed release which more rapidly releases GHB in a single part of the intestinal tract." Ex. 133-1 at Ex. C ¶ 7. According to Avadel, Jazz's amendment and arguments constitute a clear and unmistakable surrender of claim scope.

This Court disagrees. First, there is no amendment-based disclaimer. Although Jazz replaced the term "controlled release" with "sustained release," the prosecution history does not support a conclusion that "controlled release" (which Jazz replaced with "sustained release") was synonymous with the limitation Avadel seeks to import into the claims (not "releasing a majority of the drug within an hour upon exposure to intestinal pH").

Second, there is no argument-based disclaimer. Avadel argues that the prosecution history contains the requisite clarity because Jazz distinguished its present invention ("sustained release") from the prior art (which taught a "delayed release"). On the one hand, the applicant stated:

> Since [the prior art] is directed to delayed release, not sustained release . . . [the prior art's] delayed-release coatings comprise about 87% by weight pH-sensitive enteric polymers, specifically pH-sensitive methacrylic acid-methyl methacrylate co-polymers. As the coatings comprise a large percentage of pH-sensitive polymer, these dosage forms would release the majority of the drug relatively rapidly upon exposure to intestinal pH (e.g., about 6 and above), i.e., delayed release.

D.I. 133-1, Ex. B at 9. But on the other hand, Jazz consistently identified the necessary features of its invention as the DI water-based *in vitro* release profile and a sustained release coating comprised of certain co-polymers. For example, Jazz stated that:

> In contrast [to the prior art], the presently claimed invention is directed to dosage forms comprising an immediate release portion and a sustained release portion. The claimed sustained release portion releases less than 10% of the drug within an hour in DI water and at least about 40% of the drug by about four to six hours in DI water and the sustained release coating comprises about 20-50% by weight methacrylic acid-methyl methacrylate co-polymers. . . . [Aware of the teachings in the prior art, the inventors] conducted a regional GHB absorption study in humans in order to create an improved model of GHB delivery and used pharmacokinetic modeling to predict an *in vitro* release profile that would provide improved bioavailability.

D.I. 133-1, Ex. B at 9.[3] Jazz did not clearly and unmistakably assert that not "releasing a majority of the drug within an hour upon exposure to intestinal pH" is also a necessary feature of its invention. *cf. SpeedTrack, Inc. v. Amazon.*com, 998 F.3d 1373, 1378 (Fed. Cir. 2021) (finding disclaimer where applicants added a hierarchical limitation to overcome the prior art and "repeatedly highlighted predefined hierarchical field-and-value relationships as a difference between [the prior art] and the [asserted] patent"). At bottom, the prosecution history is ambiguous and does not meet the high standard for finding a disclaimer. *See Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1046 (Fed. Cir. 2016) ("When the prosecution history is used solely to support a conclusion of patentee disclaimer, the standard for justifying the conclusion is a high one. Where the alleged disavowal is ambiguous, or even amenable to multiple reasonable interpretations, we have declined to find prosecution disclaimer.") (internal quotation marks and citations omitted).

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[3] *See also* D.I. 133-1, Ex. B at 11 ("As the cited art teaches neither the presently claimed structural limitations, nor the presently claimed release profile, and one of skill in the art would have no motivation, based on the cited art, to develop a GHB formulation with the claimed *in vitro* release profile."); *Id.* (noting that the "inventors had discovered that the claimed *in vitro* release profile provides superior bioavailability as compared to the formulations in the cited art").

Finally, the extrinsic evidence demonstrates that a person of ordinary skill in the art would understand "sustained release" as plainly meaning a dosage form "in which release of the drug is extended over a period of time". *See, e.g.*, D.I. 133-1 at Ex. 3 (Dictionary of Pharmacy); *Id.* at Ex. 4 (defining "sustained release" in Webster's New Explorer Medical Dictionary as "designed to slowly release a drug in the body over an extended period of time"). Because plain and ordinary meaning is the default in claim construction, *Phillips*, 415 F.3d at 1316, the Court construes "sustained release" according to its plain meaning—"the portion of the formulation that is not immediate release and that releases over a period of time."

2. "controlled release component"

Disputed Term	Plaintiff Jazz's Construction	Defendant Avadel's Construction	The Court's Construction
"controlled release component" ('079 patent)	A formulation component with an active pharmaceutical ingredient having a release over a period of at least about 2 to about 8 hours	Resinate compositions 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	Compositions 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

While the parties agree that the patentee's lexicography governs construction of "controlled release component" and that the inventors defined "controlled release" as "having a release over a period of at least about 2 to about 8 hours," Jazz maintains the lexicography stops there. Avadel, taking the lexicography further, argues that the lexicography also includes "for example GHB resinate compositions" and therefore, "controlled release component" is necessarily "limited to compositions that achieve controlled release using ion-exchange resins."

"[C]ontrolled release component" is found in claim 1 of the '079 patent, which states:

> 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.

"[C]ontrolled release" is expressly defined in the specification:

> As used herein, the term "controlled release" refers to compositions, for example GHB resinate compositions as described herein, which are 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 . . .

See '079 patent at 6:55-7:8 (emphasis added). Given the express definition of "controlled release" in the specification, the Court will apply that definition and construe "controlled release component" as "compositions 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." *See Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998) (explaining that where "a patent applicant has elected to be a lexicographer by providing an explicit definition in the specification for a claim term," then "the definition selected by the patent applicant controls").

The Court declines to limit "controlled release component" to resinates. The use of the word "example" in the '079 patent's specification suggests that controlled release compositions may be, but are not required to be, formulated from resins. Although Avadel argues that only "the 'GHB' portion of the 'GHB resinate compositions' . . . is exemplary," D.I. 132 at 32, the definition states that "'controlled release' refers to compositions, for example GHB resinate compositions"—not that controlled release refers to resinate compositions, for example of GHB. *See* '079 patent at 6:55-7:8.

Nor does the word "example" by itself disclaim non-resinate compositions. *See, e.g.*, *Purdue Pharma L.P. v. Acura Pharms., Inc.*, C.A. No. 15-292, 2016 WL 234800, at *4 n.7 (D. Del. Jan. 19, 2016) ("[T]his exemplary discussion of a binder is not a disavowal of the full scope of the claim term and I decline to import this limitation into the claim."). Avadel relies on *Level Sleep LLC v. Sleep Number Corp.* to argue that non-resinates have been disclaimed. But there, the Court limited the claim term "low body pressure" where the specification expressly defined "low body pressure" as "below the ischemic pressure of about 30 mmHg." No. 2020-1718, 2021 WL 2934816, at *1 (Fed. Cir. July 13, 2021). Here, the specification does not contain the requisite clarity to conclude, as Avadel urges, that all compositions be limited as resinate compositions.

Avadel argues that "controlled release" should be limited to resinate compositions because the specification purportedly "makes clear that 'the present invention' is limited to resinate dosage forms." D.I. 132 at 31. But the specification describes numerous embodiments of "the present invention" without limiting the claims to resinate compositions, suggesting that while some embodiments may be accomplished through the use of resinate compositions, such resinates are not a necessary component of the claimed inventions. *See, e.g.*, '079 patent at 4:35-38; 6:42-45. Thus, describing exemplary embodiments as the "present invention" does not limit claim scope, especially where the specification does not uniformly require compositions to be resinates. *See Continental Circuits LLC v. Intel Corp.*, 915 F.3d 788, 798 (Fed. Cir. 2019) ("present invention" is not limiting "where the references . . . are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent").

Accordingly, the Court construes "controlled release component" as "compositions 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."

3. "modified release particles"

Disputed Term	Plaintiff Jazz's Construction	Defendant Avadel's Construction	The Court's Construction
"modified release particles" ('782 patent)	Plain and ordinary meaning, i.e., particles containing an active pharmaceutical ingredient with a release profile that is different from that of an immediate release particle	Particles that are resinate compositions 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	Plain and ordinary meaning, i.e., particles containing an active pharmaceutical ingredient with a release profile that is different from that of an immediate release particle

Jazz argues that "modified release particles" should be afforded its plain and ordinary meaning. Avadel argues that "modified release particles" in the '782 patent should be construed consistent with "controlled release component" in the '079 patent.

"[M]odified release particles" appears in claim 1 of the '782 patent, which recites:

> 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 cl. 1. Starting with the claim language and the specification, neither support Avadel's limitations—that is, limiting "modified release particles" to a resinate composition with the GHB releasing over a period of at least about 2 to about 8 hours. While Avadel argues that the specification's interchangeable use of "controlled" and "modified" release means that they have

the same meaning (because the patent draws no distinction between them), "controlled release" is expressly defined; "modified release" is not. And although Avadel says a person of ordinary skill in the art would understand "modified release particles" to be limited to resinates given the "specification's descriptions of the 'present invention' and disparagement of non-resinate formulations," D.I. 132 at 44, the examiner stated during prosecution that "modified release portion is broadly interpreted as being modified in some way," D.I. 133-1, Ex. 8 at 6, suggesting that a person of ordinary skill in the art would understand modified release particles as having a release profile that is different from that of an immediate release particle. *See Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005) ("Statements about a claim term made by an examiner during prosecution of an application may be evidence of how one of skill in the art understood the term at the time the application was filed.").

The extrinsic evidence further suggests that "modified release" was a term of art, meaning a release profile that is different from that of an immediate release product. *See, e.g.*, D.I. 133-1, Ex. 9 at 4 ("Modified release dosage forms are formulations where the rate and/or site of release of the active ingredient(s) are different from that of the immediate release dosage form administered by the same route."). Other courts are in accord. *See Ferring B.V. v. Mylan Pharms. Inc.*, C.A. No. 13-5909, 2014 WL 6676670, at *3 (E.D. Pa. Nov. 25, 2014) (concluding that "plain meaning of the phrase 'modified release material' as used in the patent claims means 'a material that modifies the release of the active pharmaceutical ingredient.'").

Thus, the Court will apply the plain and ordinary meaning, which is the default in claim construction. *Phillips*, 415 F.3d at 1316. "Modified release particles" means "particles containing

an active pharmaceutical ingredient with a release profile that is different from that of an immediate release particle."[4]

4. "whether the claimed 'system' includes methods of using the approved product"

Disputed Term	Plaintiff Jazz's Construction	Defendant Avadel's Construction	The Court's Construction
"whether the claimed 'system' includes methods of using the approved product" ('963 patent)	The '963 patent claims methods of using a computer-implemented system to safely distribute gamma-hydroxybutyrate for treatment of a narcoleptic patient.	The claims are directed to systems and not to methods.	The claims are directed to systems and not to methods.

The parties dispute whether claims of the '963 patent are directed to methods (as Jazz contends), or systems (as Avadel contends).

Claim 1 of the '963 patent recites:

> A computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion, comprising:
>
> > one or more computer memories for storing a single computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields;
> >
> > said prescription fields, contained within the database schema, storing prescriptions for the prescription drug with the potential for abuse, misuse or diversion, wherein the prescription drug is sold or distributed by a company that obtained approval for distribution of the prescription drug;
> >
> > said patient fields, contained within the database schema, storing information sufficient to identify the narcoleptic patient for whom the company's prescription drug is prescribed;

[4] While Avadel argues that "modified release particles" in the '782 patent should be construed consistent with "controlled release component" in the '079 patent, this Court, as described *supra*, declined to limit "controlled release component" to resinates.

> said prescriber fields, contained within the database schema, storing information sufficient to identify a physician or other prescriber of the company's prescription drug and information to show that the physician or other prescriber is authorized to prescribe the company's prescription drug;
>
> a data processor configured to:
>
> process a database query that operates over all data related to the prescription fields, prescriber fields, and patient fields for the prescription drug; and reconcile inventory of the prescription drug before the shipments for a day or other time period are sent by using said database query to identify information in the prescription fields and patient fields;
>
> wherein the data processor is configured to process a second database query that identifies that the narcoleptic patient is a cash payer and a physician that is interrelated with the narcoleptic patient through the schema of the single computer database;
>
> said identifying that the narcoleptic patient is a cash payer by said second database query being an indicator of a potential misuse, abuse or diversion by the narcoleptic patient and being used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database.

'963 patent at cl. 1. Starting with the claim language, it recites a "computer-implemented system", followed by identifying the functions of that system, to include "one or more computer memories", "prescription fields", "patient fields," "prescriber fields," and a "data processor" configured to process various queries. *Id.* Thus, the claimed system is an assemblage of components that together operate to accomplish the prescribed purpose. *See ABB Automation Inc. v. Schlumberger Resource Management Services, Inc.*, C.A. No. 01–077–SLR, 2003 WL 1700013, at *4 (D. Del., Mar. 27, 2003) (explaining that a "system" is "an integrated assemblage of hardware and/or software elements operating together to accomplish a prescribed end purpose"). To argue that the language claims a method, Jazz rewrites the claim language, omitting the recited components (e.g.,

"computer memories", "prescription fields", "prescriber fields") and inserting verbs where they do not exist (e.g., "identifying", "reconciling"). D.I. 132 at 48. But the claims, on their face, do not recite any method steps. *See In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (noting the "distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps").

Jazz alleges that, because the claims purportedly require a human to perform the steps on computer, they must be method claims. Tr. 69:10-70:23; D.I. 132 at 60. But the claims recite functional language (e.g., "the data processor is configured to process a second database query") and system components may be described as taking action without being transformed into methods. *See HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1277 (Fed. Cir. 2012) (the claim element "[a] mobile station for use with a network . . . that achieves a handover . . . by: . . . storing link data . . ." does not require that the network take the action of storing link data); *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1315-16 (Fed. Cir. 2017) ("Because the claims merely use permissible functional language to describe the capabilities of the claimed system, it is clear that infringement occurs when one makes, uses, offers to sell, or sells the claimed system.").

At the Hearing, Jazz maintained that "system" and "method" mean the same thing, arguing that "[a] system is a type of method." Tr. 93:21. But Jazz's position is strained in view of the patent's title, "Sensitive Drug Distribution System *and* Method" (emphasis added), distinguishing between a "system" and a "method." And Jazz's position is further strained given that Jazz prosecuted both system and method claims in this patent family, pursing claims to "[a] computer-implemented system" and "[a] computer-implemented method" in the same application. D.I. 133-1, Ex. R at 22.

Jazz relies on *Lyda v. CBS Corp.*, 838 F.3d 1331, 1339 (Fed. Cir. 2016) to argue that, despite using the word "system," the "purported system claims [as Avadel proposes] asserted in this case are, in fact, method claims because the body of the claims require the performance of particular method steps." D.I. 132 at 47-48 (quoting *Lyda*, 838 F.3d at 1339). But the Federal Circuit treated the claims at issue in *Lyda* as method claims when conducting a Rule 12(b)(6) analysis; that conclusion was not reached at claim construction. Also, in *Lyda*, unlike here, the claims on their face were actually directed to a system of method steps. 838 F.3d at 1335 ("A system . . .comprising . . . providing . . . having . . transmitting . . . collecting, correlating, and processing . . . [and] routing.").

For all these reasons, the Court finds the claims of the '963 patent are directed to systems, not methods.[5]

5. "[single]/[central] computer database"

Disputed Term	Plaintiff Jazz's Construction	Defendant Avadel's Construction	The Court's Construction
"[single]/[central] computer database" ('963 patent)	No construction necessary	One and only one computer database, having the recited functionality	One and only one computer database

The parties dispute whether "single computer database" and "central computer database" contemplate multiple databases distributed among multiple commuters so long as they are under

[5] While the claims of the '936 patent are directed to systems, and not methods, Avadel has not waived arguing that the claims recite both a system and the method steps of using the system and are accordingly indefinite under 35 U.S.C. § 112. *See IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005).

an entity's central control (as Jazz suggests), or whether those terms contemplate one and only one database to perform the recited functions (as Avadel suggests).

Claims 1-23 require:

> one or more computer memories for storing a single computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields; . . . .

'936 patent at cl. 1-23. Claims 25 and 28 depend from claim 24, which requires:

> one or more computer memories for storing a central computer database of the company that obtained approval for distribution of the prescription drug, for receiving prescriptions from any and all patients being prescribed the company's prescription drug, said central computer database having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields; . . . .

'936 patent at cl. 24. Starting with the claim language, the claims use the term "single computer database" and "central computer database" as opposed to one or more databases or multiple databases. "One or more" and "multiple" are both used in other limitations, but not for the computer database itself, which is always "single." Turning to the specification, it discusses "the central database" and illustrates that, while the applicants knew how to use words like "multiple", they did not choose that language for the central database, which is always singular. *See, e.g.*, '963 patent at 1:48-53 ("Information is kept in a central database" and abuses are identified "by monitoring data in the database."); *Id.* at 2:20-25 ("The exclusive central database contains all relevant data . . . . Several queries and reports are run against the database to provide information which might reveal potential abuse of the sensitive drug, such as early refills."). Thus, the intrinsic record favors a construction that only one database can perform the recited functionality.

Jazz asserts that the term "single" suggest exclusivity of control. Tr. 102:11-16 ("A database . . . is just some kind of storage or data, you want to call one or 15 of them, as long as I

control all of them and I can do that query to find out if that guy is doctor shopping, that's what matters."). But the claim doesn't say multiple computer databases under common control. The claim language says a "single" database. And in claims 25 and 28, "central computer database" means "single computer database."

"Single" means "one and only one." *See* D.I. 133-1, Exs. L, M. The Court will construe "single computer database" and "central computer database" to mean "one and only one computer database."

6. "reconcile inventory/reconciling inventory/cycle counted and reconciled"

Disputed Term	Plaintiff Jazz's Construction	Defendant Avadel's Construction	The Court's Construction
"reconcile inventory/reconciling inventory/cycle counted and reconciled" ('963 patent)	No construction necessary	Checking whether there is a mismatch between the aggregate amount of a drug reported in physical inventory and the aggregate amount in the database	Checking whether there is a mismatch between the amount of a drug reported in physical inventory and the amount in the database

The parties agree that "reconciling inventory" means confirming that the inventory at a particular location matches what is expected based on the information in the database, D.I. 132 at 76; Tr. 112:2-10, but dispute whether that mismatch requires tabulating "aggregate" amounts.

Starting with the claim language, claim 1 requires "a data processor configured to: . . . reconcile inventory of the prescription drug before the shipments for a day or other time period are sent by using said database query to identify information in the prescription fields and patient fields." '963 patent at cl. 1. If the plain meaning of "to reconcile" in this context means to bring multiple things into agreement, claim 1 does not explain what is being brought into agreement with what.

The prosecution history suggests that "inventory reconciliation involves a physical check being made with respect to the physical inventory and then compared to a database system inventory value to determine whether the physical inventory matches the database inventory value." D.I. 133-1, Ex. Q at 11. When distinguishing their claims over prior art, the applicants stated: "[The prior art] merely checks whether a pharmacy has a sufficient amount of the medication to fulfill a specific prescription order. There is no disclosure of checking whether there is a mismatch between the aggregate amount of a drug in physical inventory with the aggregate amount in the database as required by the inventory reconciliation features of claim 1." *Id.*

Based upon the intrinsic record, the Court will construe "reconciling inventory" to mean "checking whether there is a mismatch between the amount of a drug reported in physical inventory and the amount in the database." To import the term "aggregate" in the construction would render claim 20 (dependent on claim 1) superfluous as it includes aggregate inventory reconciliation, but is not limited by aggregate inventory reconciliation. *See* '963 patent at cl. 20. ("The system of claim 1, wherein current inventory is cycle counted and reconciled with database quantities before shipments for a day or other time period are sent.").

IV. CONCLUSION

The Court will adopt the parties' agreed-upon construction of claim term "by about 4 to about 6 hours" and construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

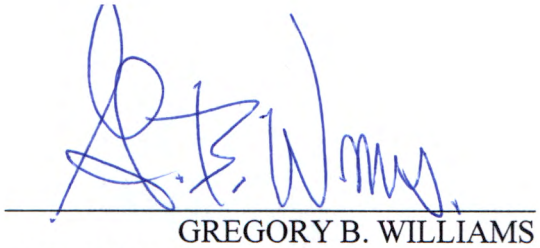
JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-GBW
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW

ORDER

At Wilmington this 18th day of November 2022:

For the reasons set forth in the Memorandum Opinion issued this day, IT IS HEREBY ORDERED that the Court construes the following claim terms of U.S. Patent Nos. 8,731,963 ("the '963 patent"), 10,758,488 ("the '488 patent"), 10,813,885 ("the '885 patent"), 10,959,956 ("the '956 patent"), 10,966,931 ("the '931 patent"), 11,077,079 ("the '079 patent"), and 11,147,782 ("the '782 patent") as follows:

Claim Term	**Court's Construction**
Disputed Constructions	
"sustained release portion" ('488 patent; '885 patent; '956 patent; '931 patent)	Plain and ordinary meaning, i.e., the portion of the formulation that is not immediate release and that releases over a period of time
"controlled release component" ('079 patent)	Compositions 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
"modified release particles" ('782 patent)	Plain and ordinary meaning, i.e., particles containing an active pharmaceutical ingredient with a release profile that is different from that of an immediate release particle
"whether the claimed 'system' includes methods of using the approved product" ('963 patent)	The claims are directed to systems and not to methods.
"[single]/[central] computer database" ('963 patent)	One and only one computer database
"reconcile inventory/reconciling inventory/cycle counted and reconciled" ('963 patent)	Checking whether there is a mismatch between the amount of a drug reported in physical inventory and the amount in the database
Agreed-Upon Construction	
"by about 4 to about 6 hours" (the '488, '885, '956 and '931 patents)	Plain and ordinary meaning, which is at any point prior to approximately 4 hours or at any point prior to approximately 6 hours



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE