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 (MN)
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	)	C.A. No. 21-1138 (MN)
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	)	C.A. No. 21-1594 (MN)

JOINT CLAIM CONSTRUCTION BRIEF

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TABLE OF ABBREVIATIONS

- **"'963 Patent"** refers to U.S. Patent No. 8,731,963.
- **"'488 Patent"** refers to U.S. Patent No. 10,758,488.
- **"'885 Patent"** refers to U.S. Patent No. 10,813,885.
- **"'956 Patent"** refers to U.S. Patent No. 10,959,956.
- **"'931 Patent"** refers to U.S. Patent No. 10,966,931.
- **"'079 Patent"** refers to U.S. Patent No. 11,077,079.
- **"'782 Patent"** refers to U.S. Patent No. 11,147,782.
- **"Avadel"** refers to Avadel CNS Pharmaceuticals LLC.
- **"Cash payer terms"** refers to the disputed claim terms "database query that identifies that the narcoleptic patient is a cash payer" / "database queries . . . for identifying: that the narcoleptic patient is a cash payer".
- **"Defendant"** refers to Avadel.
- **"EDS"** refers to excessive daytime sleepiness.
- **"GHB"** refers to gamma-hydroxybutyrate.
- **"Jazz"** refers to Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited, collectively.
- **"NDA"** refers to a New Drug Application.
- **"Plaintiffs"** refers to Jazz.
- **"Reconciling inventory terms"** refers to the disputed claim terms "reconcile inventory" / "reconciling inventory" / "cycle counted and reconciled".
- **"REMS Patent"** refers to the '963 patent.
- **"Resinate Patents"** refers to the '079 and '782 patents.[1]

[1] Jazz disagrees with this characterization of the '079 and '782 patents and this definition is used solely by Defendant.

- **"Sustained Release Patents"** refers to the '488, '885, '956, and '931 patents, collectively.

I. INTRODUCTION AND BACKGROUND

A. Jazz's Introduction and Background

1. Jazz's Introduction

This Hatch-Waxman litigation involves seven patents from three different families, all of which cover various novel aspects of the drug GHB. GHB treats cataplexy and EDS in patients with narcolepsy.

The first patent family[2] claims sustained release GHB formulations and methods of using those formulations to treat cataplexy or EDS. There are two disputed terms from this family: "sustained release portion" and "by about 4 to about 6 hours." Jazz proposes that "sustained release portion" carries its plain and ordinary meaning. In contrast, Defendant Avadel seeks to read a specific drug release profile into the term, which is different than the release profile already set forth in the claims and unsupported by the intrinsic record for the Sustained Release Patents. Jazz further proposes that "by about 4 to about 6 hours" carries its plain and ordinary meaning: "by approximately 4 to approximately 6 hours." Avadel proposes to read in an additional limitation unsupported by the intrinsic record.

The asserted claims of the second patent family (the '079 and '782 patents) are also directed to GHB formulations and pharmaceutical compositions containing those formulations. The parties dispute one term in each patent. *First*, the parties dispute the meaning of "controlled release component," which appears in the claims of the '079 patent. The disputed term is defined in the specification, and Jazz proposes that the patentee's lexicography governs. Avadel seeks to alter that lexicography, in violation of Federal Circuit precedent, to limit the term to a specific "example": "resinate compositions." *Second*, the parties dispute the meaning of "modified release

[2] The '488, '885, '956, and '931 patents.

particles," which appears in the claims of the '782 patent. Jazz proposes that this term carries its plain and ordinary meaning. Avadel asks the Court to read two limitations into the claimed "modified release particles" in the absence of any intrinsic support.

The third patent family (the '963 patent) claims methods of safely distributing drugs prone to abuse, misuse, and diversion, such as GHB. The parties dispute four terms: (1) "computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion"; (2) "[single]/[central] computer database"; (3) "reconcile inventory" / "reconciling inventory" / "cycle counted and reconciled"; and (4) "database query that identifies that the narcoleptic patient is a cash payer" / "database queries . . . for identifying: that the narcoleptic patient is a cash payer". For the first term, Jazz submits that the claims cover methods of using a computer-implemented system to safely distribute GHB for treatment of a narcoleptic patient. For the remaining terms, Jazz submits no construction is necessary, as each is readily understood by a POSA. To support its noninfringement and invalidity positions, and without intrinsic support, Avadel improperly reads limitations into each disputed term.

For at least these reasons, and those discussed below, this Court should adopt Jazz's proposed constructions.

2. Jazz's Background

Xyrem® and Xywav®: For the past twenty years, Jazz has been the industry leader in developing treatments for narcolepsy. Narcolepsy manifests in debilitating ways, causing an overwhelming desire to fall asleep during the day, known as EDS. People with narcolepsy may also experience sudden loss of muscle control during the day, known as cataplexy. Xyrem® was approved by the FDA in 2002 for the treatment of cataplexy, and in 2005 for the treatment of EDS, in patients with narcolepsy. Xyrem® has proven to be a life-changing treatment for thousands of Americans.

Xyrem®'s success allowed Jazz to reinvest in research and development, including research focused on improving Xyrem®. The active ingredient in Xyrem® is sodium oxybate, the sodium salt of GHB. Xyrem® patients receive a significant amount of sodium at the recommended dosage. Jazz spent years developing Xywav®, which contains 92% less sodium than Xyrem® but the same amount of oxybate. The FDA approved Xywav® in 2020 for the treatment of EDS and cataplexy in patients with narcolepsy. Shortly after the approval of Xywav®, FDA confirmed that the difference in the sodium content between Xywav® and Xyrem® at the recommended doses will be clinically meaningful in reducing cardiovascular morbidity in a substantial proportion of patients for whom the drug is indicated.

Once-Nightly Formulations Discovered and Claimed in the Patents-in-Suit:

Both Xyrem® and Xywav® include instructions for dosing once at bedtime, and then again 2.5 to 4 hours later. To avoid the need to wake up after first going to sleep to take a second dose of medication, Jazz undertook efforts to develop a once-nightly formulation of GHB. Six of the Patents-in-Suit stem from Jazz's ongoing efforts to develop once-nightly GHB formulations (the seventh is the REMS patent). Specifically, Jazz discovered formulations comprised of both immediate release drug particles (to help the patient fall asleep right away) and sustained/controlled/modified-release particles (to help the patient stay asleep throughout the night), as well as methods of using those formulations for the treatment of EDS and cataplexy.

Avadel's Infringing Sodium Oxybate Product: Avadel seeks FDA-approval for a once-nightly sodium oxybate product, which it refers to as "FT218" in its 505(b)(2) NDA. Xyrem® is the Reference Listed Drug for FT218, the sale and use of which will infringe the Patents-in-Suit.

B. Avadel's Introduction

Claim construction is often dispositive of issues in a patent litigation. It has heightened importance in this case, where a plain meaning construction of Jazz's '963 patent claims as

"systems" rather than "methods" will resolve the parties' dispute over whether that patent, directed to a REMS for distribution of a sensitive drug product, is properly listed in the Orange Book. While Avadel has always contended that Jazz's listing of the '963 patent is improper, the implications of that error have been compounded by the FDA's recent decision requiring Avadel to certify to the '963 patent. As a result, Avadel's NDA for its novel sodium oxybate drug product, FT218, presumptively cannot be approved until the '963 patent expires in June 2023. Delisting the '963 patent following claim construction would end the statutory stay—the only impediment Avadel is aware of for FT218 to obtain full FDA approval, thereby affording narcolepsy patients access to a ground-breaking improvement.

Avadel is an innovative drug company. Its novel product, FT218, can be given to narcolepsy patients once nightly—an accomplishment Jazz has tried in vain to achieve for over a decade. Jazz's two marketed oxybate products, Xyrem® and Xywav®, require twice nightly dosing, meaning that narcolepsy patients (*i.e.*, people already suffering from a sleep disorder) need to wake up in the middle of the night to take a second dose. As physicians and patients alike have publicly noted, FT218 is a game-changing formulation for those suffering from narcolepsy.

The main dispute over the '963 patent is straightforward: *are the claims directed to systems or methods*? The unambiguous language of the claims resolves that dispute, particularly in light of the other intrinsic evidence. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). This is precisely such a case. A "system" of computer memories and data processors is not a "method," and the fact that the '963 patent claims recite the intended functionality of the claimed

systems does not transform them into methods as Jazz proposes. Indeed, Jazz obtained method claims in other patents in the same family as the '963 patent, but consciously chose to prosecute the claims at issue here as "systems" rather than "methods."

The remaining '963 patent disputes are also straightforward. Avadel proposes constructions based on the claims' plain language as informed by the specification and prosecution history, while Jazz seeks to evade that plain language so it can maintain its infringement case.

As to the Sustained Release Patents, Avadel's proposed construction of "sustained release" tracks Jazz's arguments made during prosecution to overcome prior art, whereas Jazz's proposal seeks to construe the claims to cover precisely what Jazz distinguished. For "by about 4 to about 6 hours," Avadel proposes giving "by" its ordinary meaning of "not later than."

For the Resinate Patents, the parties dispute the construction of the terms "controlled release composition" and "modified release particles." As the specification makes clear, "controlled release" is limited to a specific type of dosage form: ion-exchange resins (resinates). "Modified release particles" is similarly limited because the specification uses the terms "modified release" and "controlled release" interchangeably.

II. AGREED-UPON CONSTRUCTIONS

The parties have not agreed upon any constructions.

III. DISPUTED CONSTRUCTIONS

A. The Sustained Release Patents

1. "Sustained Release Portion" / "Sustained Release"

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
"sustained release portion" (Jazz)	Plain and ordinary meaning, i.e., the portion of the formulation that	A gradual, extended release, as opposed to releasing a majority of

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
"sustained release" (Avadel)	is not immediate release and that releases over a period of time	the drug within an hour upon exposure to intestinal pH

a) Jazz's Opening Position

The parties dispute the meaning of the claim term "sustained release" / "sustained release portion,"[3] as shown bolded in the relevant part of Claim 1 of the '488 patent (Ex. 1),[4] below:[5]

> 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 . . . .

[3] The Court should construe "sustained release portion" because it is improper to pick apart pieces of a phrase for purposes of claim construction. *See Lo v. Microsoft Corp.*, No. 07-322, 2009 WL 2960427, at *8 (E.D. Tex. June 11, 2009) (where construing words in a phrase "separately would disjoin [a] relationship that is taught throughout the [intrinsic record] and effectively preclude a proper contextual construction," the "appropriate construction should consider the entire phrase and not handle it piecemeal"). Jazz's construction is still correct, however, even if the Court construes just "sustained release."

[4] The '488 patent is representative of all the Sustained Release Patents.

[5] All emphasis throughout both parties' portions of this joint brief added unless otherwise indicated.

As explained below, Jazz's proposal is supported by the claim language, the intrinsic record, and extrinsic evidence. Avadel's proposal, on the other hand, seeks to read an additional, unsupported release profile into the claims and runs afoul of Federal Circuit precedent.

(1) The claim language supports Jazz's construction

Claim construction starts with the words of the claims. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 (Fed. Cir. 2003). Only Jazz's proposed construction is consistent with the claim language. Specifically, the claims require that the formulation comprise both "immediate release and sustained release portions." The claims thus distinguish between the immediate and sustained release portions of the formulation, and Jazz therefore proposes that the Court construe "sustained release portion" in a manner that distinguishes it from the immediate release portion (i.e., as "the portion of the formulation that is not immediate release and that releases over a period of time").

Avadel's proposed construction seeks to rewrite the claim language to introduce an additional, unsupported dissolution profile. Avadel proposes that the Court construe "sustained release" to include specific time- and pH-dependent drug release characteristics (i.e., "gradual, extended release" that does not release "a majority of the drug within an hour upon exposure to intestinal pH"). But the claims already expressly set forth the specific dissolution profile, in the specific media, that any "sustained release portion" of the claimed formulation must have: "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 . . . ." Thus, Avadel's proposal ignores the words already set forth in the claims and attempts to replace them with other words. The Court should reject Avadel's attempt to substitute different language and a different dissolution profile into the claims. *See, e.g.*, *Home Semiconductor Corp. v. Samsung Elecs. Co.*, 701 F. App'x 1006, 1011 (Fed. Cir. 2017) ("the Board injected ambiguity into its claim

construction by replacing the claim term 'over' with 'above'"); *Wyeth, LLC v. Intervet, Inc.*, 771 F. Supp. 2d 334, 346 (D. Del. 2011) (construction that "replaces the word 'vaccine' with the term 'pharmaceutical composition'" was improper); *In re Body Sci. LLC Pat. Litig.*, 167 F. Supp. 3d 152, 160-61 (D. Mass. 2016) (rejecting construction that "effectively replaces [one] word" in the claims with another, because "the drafter's choice to use the word [in the claims] should be given substantial effect").

(2) The intrinsic record supports Jazz's construction

To the extent Avadel contends that its proposal does not seek to replace the claimed dissolution profile (measured in deionized water), but instead seeks to add a second dissolution requirement that is not claimed (measured in intestinal pH), Avadel would be asking this Court to improperly add a claim limitation in the absence of any clear disavowal of claim scope in the intrinsic record. This too is improper. *See EMC Corp. v. Pure Storage, Inc.*, No. 13-1985, 2016 WL 402580, at *4 (D. Del. Feb. 2, 2016) ("[T]he rule against importing limitations from the specification into the claims absent express disavowal of claim scope both militate against adopting Pure's proposed construction"). The intrinsic record provides no support for this additional limitation, and instead, clearly supports Jazz.

Consistent with the intrinsic record, the plain and ordinary meaning of "sustained release portion" is "the portion of the formulation that is not immediate release and that releases over a period of time." This is precisely how the term is used in the intrinsic evidence, as the applicants made clear during prosecution that the sustained release portion of the claimed formulation is the portion of the formulation that is not immediate release and that instead releases over a period of time; the period of time was not specified. *See* Ex. 2 at 8-9 ("Sustained release formulations . . . provide for a more gradual, but extended release of the drug over a period of time. Such a formulation could start releasing the drug shortly after dosing, or there could be a lag before the

drug starts to release."). That same meaning is reflected in the specification. *See* Ex. 1 at 16:12-13 ("[S]ustained delivery of GHB to the patient over a prolonged period of time.").

There is nothing in the intrinsic record that would warrant importing a negative limitation (as Avadel proposes) to exclude any "sustained release portion" that releases a majority of the drug within an hour upon exposure to intestinal pH. *See Sprint Commc'ns Co. L.P. v. Cequel Commc'ns, LLC*, No. 18-1919, 2020 WL 3048175, at *7 (D. Del. June 8, 2020) ("Absent any express disclaimer or independent lexicography in the written description that would justify adding [a] negative limitation, [the Court] will not import one."). Instead, the specification is consistent with the already-claimed dissolution profile, as measured according to the claim in a specific dissolution apparatus in deionized water at a temperature of 37° C. *See* Ex. 1 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.").

Indeed, Avadel ignores that the '488 patent's specification provides examples of other dissolution media that could be employed in certain embodiments, one of which is "simulated intestinal fluid." *Id.* at 8:4. That media, however, is ***not*** the media that the applicants chose to recite in their claims, and Avadel has no basis to rewrite the claim language to include limitations based on what happens when the sustained release portion is "expos[ed] to intestinal pH." The Court should reject Avadel's proposed construction and adopt Jazz's.

(3) The extrinsic evidence supports Jazz's construction

The court may also look to extrinsic evidence. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995). The extrinsic evidence supports Jazz's proposal.

"Sustained Release" is a term of art with a plain meaning readily understood at the time of invention. *See, e.g.*, Ex. 3 (defining "sustained release" as a dosage form "in which release of the

drug is extended over a period of time"); Ex. 4 (similar). Thus, both the intrinsic and extrinsic evidence supports Jazz's construction, and Jazz's construction should be adopted.[6]

b) Avadel's Answering Position

The parties dispute the scope of drug release encompassed by "sustained release."[7] Jazz proposes a construction that covers *any* type of release that is not "immediate" and "that releases over a period of time." All releases happen over *some* period of time, however, and Jazz's proposal does not provide any guidance as to what time period is long enough to distinguish from a supposedly immediate release: 1 minute? 5 minutes? 20 minutes? Avadel's proposal answers that question by adopting the explanation Jazz gave during prosecution that "sustained release" referred to "a gradual, extended release, as opposed to releasing a majority of the drug within an hour upon exposure to intestinal pH." Jazz added the "sustained release" term and provided that explanation to distinguish prior art, and cannot now argue for scope that it unambiguously surrendered.

(1) Jazz Clearly and Unmistakably Surrendered Claim Scope

The originally-filed claims of the application that led to the '488 patent (to which the Sustained Release Patents all claim priority) did not contain the "sustained release" limitation. Rather, the claims were initially directed to formulations with "controlled release" portions. '487 Application File History, 3/6/2020 Amendments at 2 (striking "controlled" and adding "sustained.") (attached as Ex. A). The Examiner rejected those claims as obvious over a prior art

[6] Jazz's construction is also consistent with courts in this District that have been asked to construe "sustained release." *See, e.g.*, *Teva Pharms. USA, Inc. v. Forest Labs., Inc.*, No. 13-2002, 2015 WL 4143277, at *3 (D. Del. July 9, 2015) (construing "sustained release" as "release that is delayed and/or extended" based upon its plain meaning supported by the specification).

[7] Jazz argues that the Court should construe the phrase "sustained release *portion.*" *Supra* at 6 n.2. This appears to be an improper attempt to run from Jazz's repeated prosecution arguments limiting the scope of "sustained release." But even if the Court construes "sustained release portion," the disclosures relating to "sustained release" throughout the intrinsic record would still apply.

patent application filed by Liang et al. (U.S. Pat. Pub. No. 2006/0210630; "Liang"), finding that Liang disclosed a GHB dosage form with a "controlled release." '487 Application File History, 3/6/2020 Applicant Remarks at 9 (attached as Ex. B).

To overcome this rejection, Jazz amended the claims to replace "controlled release" with "sustained release." Ex. A at 2-5. Jazz concurrently submitted Remarks and a declaration from one of the named inventors, Clark Allphin. '487 Application File History, 3/6/2020 Applicant Remarks; '487 Application File History, 3/6/2020 Declaration of Clark Allphin (the "Allphin Declaration") (attached as Ex. C).

Jazz explained that its amendment to "sustained release" formulations narrowed the claims. Jazz thus argued that "the release profile of the claimed invention is *distinct* from that taught in Liang." Ex. B at 8. According to Jazz, "[t]he presently claimed invention is directed to an oxybate formulation with a *sustained release* component. Liang however, teaches a *delayed release* formulation. These formulations are quite different structurally and functionally, and it would not be obvious to modify a delayed release formulation to make a sustained release formulation." *Id*. (emphasis in original).

Jazz was clear and unequivocal about the scope of the amended claims, arguing that "sustained release" formulations "provide for a more gradual, but extended release," as opposed to delayed release formulations like those in Liang that "quickly release the majority of the drug":

> Delayed release formulations *quickly release the majority of the drug a certain amount of time after dosing*. Essentially a patient is given a delayed bolus dose. *Sustained release formulations, in contrast*, provide for a *more gradual, but extended release* of the drug over a period of time. Such a formulation could start releasing the drug shortly after dosing, or there could be a lag before the drug starts to release. *This sustained release of the drug can take place over a longer period of time than would typically occur in a delayed*

> *release formulation*.

Id.; Ex. C at ¶ 3 ("This sustained release formulation provides for a *gradual, but extended* release of GHB over a period of time").

Jazz also specifically distinguished Liang, which it argued released the majority of the drug "within an hour" "upon exposure to intestinal pH":

> As [Liang's] 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. As shown in Example 7 and Figures 1 and 2 of Liang, these "*delayed release* prototypes" release *about 70%-100% of the drug within an hour at intestinal pH*.

Ex. B at 9; *see also* Ex. C at ¶ 6 ("[Liang's] pH sensitive coatings would release GHB relatively rapidly, i.e., in about an hour, upon exposure to intestinal pH."). According to Mr. Allphin, "[o]ur aim was to develop GHB formulations that . . . proved (sic) sustained release throughout the ileum and jejunum [portions of the intestine], *rather than Liang's delayed release which more rapidly releases GHB in a single part of the intestinal tract*." Ex. C at ¶ 7. Relying on Jazz's amendment and arguments, the Examiner withdrew the rejection over Liang.

By both amending the claims and clearly and unambiguously asserting that its "sustained release" was different from Liang's "delayed release," which Jazz argued rapidly releases GHB upon exposure to intestinal pH, Jazz committed to the meaning of "sustained release" set forth in Avadel's proposed construction. Jazz "rejected [a] broad assessment of the claim scope and stated in a public record what its invention could not be." *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1327 (Fed. Cir. 2003) (finding disavowal based on applicant's repeated insistence of its invention as different from prior art); *SpeedTrack, Inc. v. Amazon.com*, 998 F.3d 1373, 1379-80 (Fed. Cir. 2021) (finding claims to computer systems "exclude predefined field-and-value relationships" when "applicants repeatedly highlighted" such relationships "as a difference

between" the prior art and claimed invention); *Sensormatic Electronics, LLC v. Genetec (USA) Inc.*, C.A. No. 20-760-MN, D.I. 68, at 9 (D. Del Sep. 29, 2021) (finding disclaimer where applicant added the limitation "detecting moving objects [within said / in the] selected monitoring area" and made remarks to overcome an anticipation rejection) (attached as Ex. D).

Jazz's amendment and arguments constitute a clear and unmistakable surrender of claim scope. In Jazz's own words, "sustained release" is limited to a "gradual, extended release" and cannot encompass "delayed release," as in Liang, because the Liang formulation allegedly releases the majority of the drug within an hour upon exposure to intestinal pH. The proper construction of "sustained release" should incorporate Jazz's disclaimer. *See MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330 (Fed. Cir. 2007) (finding prosecution arguments that distinguish the art to be "useful" because "they indicate in the inventor's own words what the invention is not"); *Tech. Props. Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1359 (Fed. Cir. 2017) ("We hold that the district court's narrowing construction based on [the prior art]—'whose frequency is not fixed by any external crystal'—properly encapsulates the patentee's disclaiming statements."). Avadel's proposal incorporates Jazz's exact words to capture Jazz's disavowal.

Jazz criticizes Avadel for "importing a negative limitation," (*supra* at 9), but Avadel's proposed construction tracks the precise language Jazz used to distinguish Liang and obtain allowance. The Federal Circuit and courts in this district have repeatedly held that a negative limitation is proper where, as here, it is supported by such an "express disclaimer."[8] *Omega*, 334 F.3d at 1323; *see also Tech. Props.*, 849 F.3d at 1358-59 (affirming the district court's construction

[8] It is irrelevant whether Jazz made additional arguments regarding the prior art. *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007) ("[A]n applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well.").

of "entire oscillator" as one "whose frequency is *not* fixed by any external crystal" based on an applicant's statements that its invention "must be a variable frequency oscillator rather than a fixed-frequency crystal"); *Transcend Med., Inc. v. Glaukos Corp.*, C.A. No. 13-830-MSG, 2015 WL 263612, at *8 (D. Del. Jan. 16, 2015) (adopting negative limitation "necessary to ensure that the disputed term is construed consistently with the disavowal made during [patent] prosecution").

Jazz should not be allowed to argue for a narrow claim interpretation to secure issuance only to turn around and seek a broad one that recaptures the disclaimed subject matter in litigation. *See Speedtrack*, 998 F.3d at 1380 (holding the doctrine of prosecution history disclaimer "ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers") (internal citation omitted). Moreover, Jazz's disclaimer applies to all the Sustained Release Patents because they all derive from the same application and were issued after the amendment and arguments at issue. *See Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1371 (Fed. Cir. 2014) ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation.") (internal citation omitted).

(2) Jazz's Proposal Is Inconsistent with the Intrinsic Evidence

Jazz contends that its "plain meaning" construction is supported by the intrinsic evidence. *Supra* at 7-9. Not so. Jazz's proposed construction is calculated to encompass *any* drug release profile modified in *any* way. Indeed, Jazz acknowledges that "the period of time" over which its proposal allows a drug to be released is unspecified, and thus can be *any* period of time. *Supra* at 8. Putting aside the fact that Jazz's construction is untenable given the disclaimer discussed above, it is also at odds with the repeated disclosures in the specification that refer to the invention as releasing over a prolonged period of time. *See e.g.*, '488 patent at 5:16-25; 8:7-11; 8:44-49; 8:49-

52. Even the sole specification excerpt cited by Jazz emphasizes "sustained delivery" of drug over a "prolonged" period of time and is inconsistent with the "any" time period implicit in Jazz's proposed construction. *See supra* at 9; '488 patent 16:12-13 (describing the controlled release portion as providing a "*sustained delivery* of GHB to the patient over a *prolonged* period of time"). By contrast, Avadel's proposed construction—a "gradual, extended release"—is congruent with the specification's disclosures that the release happens over a "prolonged" period of time.

Turning to the prosecution history, Jazz's efforts to cabin its clear and unmistakable disclaimer fail. First, Jazz argues that its prosecution argument that "sustained release" means "could start releasing the drug shortly after dosing, or there could be a lag before the drug starts to release" supports its proposed construction because it does not specify a time period for release. *Supra* at 8-9 (citing '487 Application, 3/6/2020 Remarks at 9). But Jazz quotes its prosecution argument out of context, and the Court must review the prosecution statements "as a whole." *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 20-985-RGA, 2022 WL 1026983, at *4 (D. Del. Apr. 6, 2022) (citing *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999)) (finding "clear and unmistakable disclaimer when considering the prosecution history as a whole"). When read as a whole, the entirety of Jazz's prosecution argument *does* specify a time period for "sustained release" that *does not include* releasing a majority of the drug within an hour upon exposure to intestinal pH. In the sentences preceding Jazz's quotation, Jazz specifically contrasted its "sustained release" formulation to the prior art. According to Jazz, while Liang's formulations "*quickly release* the majority of the drug a certain amount of time after dosing," "[s]ustained release formulations, *in contrast*, provide for a more *gradual, but extended* release of the drug over a period of time." *See* Ex. B at 8-9.

Next, Jazz argues that Avadel impermissibly "seeks to rewrite the claim language *to*

introduce an additional, unsupported dissolution profile." *Supra* at 7, *see also id.* at 8-9 (arguing in the alternative that Avadel's construction "seeks to add a second dissolution requirement that is not claimed (measured in intestinal pH)"). That is demonstrably incorrect. To be sure, the claims include *in vitro* dissolution profiles. *See, e.g.*, '488 patent at claim 1, elements c-d. However, Jazz ignores entirely the fact that the claims *already contained those dissolution profile limitations when they were rejected over Liang*; the amendment and arguments concerning "sustained release" came thereafter and have independent meaning. *See supra* III.A.1.b)(1).; Ex. A at 3 (showing the claimed dissolution profile as previously included in elements 1[e-f]). And, crucially, Jazz did not even attempt to distinguish Liang based on those claimed dissolution profiles. *See supra* III.A.1.b)(1); Ex. B at 8-11. Rather, as addressed above, Jazz amended the claims from being directed to "controlled release" to "sustained release" and argued that the claims were patentable over Liang because, as "sustained release" formulations, they do not cover the release within an hour at intestinal pH as disclosed in Liang. *See supra* III.A.1.b)(1).; Ex. B at 8-9. That the '488 patent specification also contains examples of other dissolution media including "simulated intestinal fluid" (*supra* at 9) does not detract from Jazz's disclaimer of a formulation that releases a majority of the drug within an hour upon exposure to intestinal pH.

The intrinsic evidence uniformly supports Avadel's construction.

(3) Jazz's Reliance on Extrinsic Evidence Is Improper

Finally, Jazz's reliance on certain extrinsic evidence purporting to show the meaning of "sustained release" (*supra* at 9-10), is improper. *See Bell Atl. Network Servs. v. Covad Commc'ns Grp.*, 262 F.3d 1258, 1268-69 (Fed. Cir. 2001) ("[I]f the meaning of the claim limitation is apparent from the intrinsic evidence alone, it is improper to rely on extrinsic evidence . . . ."). When, as here, the "disavowal of claim scope . . . is clear and unmistakable in the record before" the Court, "[extrinsic] evidence cannot properly overcome the clarity" of the disavowal. *Genuine Enabling*

Tech. LLC v. Nintendo Co., Ltd., 29 F.4th 1365, 1374-75 (Fed. Cir. 2022) (district court erred by relying on expert declaration to contradict prosecution history disclaimer); *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1143–46 (Fed. Cir. 2005) (rejecting broad dictionary definitions of "board" that include non-wooden boards in light of prosecution history that disclaimed such prior art).

And even in the "rare" circumstance where the intrinsic record is not sufficiently clear—which is not the case here—extrinsic evidence "may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history." *Bell Atl.*, 262 F.3d at 1269. Even if the Court were to consider Jazz's dictionary definition of "sustained release," that definition contradicts what Jazz told the PTO. Finally, *Teva Pharms. USA, Inc. v. Forest Labs., Inc.*, C.A. No. 13-2002-GMS, 2015 WL 4143277, at *3 (D. Del. July 9, 2015), relied upon by Jazz, is inapposite, as it did not involve any disclaimer.

c) Jazz's Reply Position

(1) No clear and unmistakable disavowal of claim scope

Avadel's position for this term is based on its theory that Jazz disclaimed a pH-based intestinal *in vivo* release profile during prosecution. *Supra* at 10-16. Avadel is incorrect.

First, there is no amendment-based disclaimer. As Avadel correctly recognizes, Jazz replaced the term "controlled release" with "sustained release." *Id.* at 10-11. Nowhere does Avadel argue (nor could it credibly do so) that "controlled release" is synonymous with the pH-based intestinal *in vivo* release profile that Avadel seeks to exclude from the scope of the claims. As such, the changing of "controlled release" to "sustained release" does not support reading Avadel's proposed negative limitation into the claims.

Second, there is no argument-based disclaimer. Avadel incorrectly argues that Jazz distinguished the prior art (Liang) by discussing a pH-based intestinal *in vivo* release profile disclosed therein and "did not even attempt to distinguish Liang based on th[e] claimed [deionized

("DI") water-based *in vitro*] dissolution profiles." *Id.* at 16. Avadel is wrong. Jazz distinguished its inventions by discussing the DI water-based *in vitro* release profile recited in the claims, not the pH-based intestinal *in vivo* release profile that Avadel seeks to exclude.

Specifically, Jazz explained during prosecution that, "[i]n contrast [to Liang], 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." *See* Ex. 2 at 9. Jazz thus made clear that its sustained release formulations were patentable over Liang due to the claimed DI-water based *in vitro* release profile and the claimed sustained release coating comprised of certain co-polymers. In fact, Jazz specifically argued that because Liang taught "neither the presently claimed structural limitations [i.e., the sustained release coating], nor the presently claimed release profile, . . . 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.* at 11. Jazz further explained that the "inventors had discovered that the ***claimed in vitro release profile*** provides superior bioavailability as compared to the formulations in the cited art." *Id.*

These statements do not clearly and unmistakably surrender the *in vivo* claim scope that Avadel proposes. To the contrary, the inventor distinguished the inventions based on the claimed *in vitro*, not any *in vivo*, release profile. *See, e.g.*, Avadel Ex. C at ¶ 9 ("[A] sustained release formulation would provide improved bioavailability. Specifically, that sustained plasma levels can be reached with a formulation that has an ***in vitro release profile wherein a significant amount of drug is released within 4-6 hours when tested in dissolution apparatus 2 in deionized water*** .

. . .”). In fact, the inventor made clear the invention was based on *in vitro* testing at “neutral pH,” and not on any intestinal pH (like Avadel seeks to add to the claim). *See id.* at ¶ 10 (“[W]e targeted a sustained release formulation . . . wherein the sustained release portion releases less than 10% of its GHB within the first hour and at least about 40% of its GHB by 4 to 6 hours when it is tested ***at a neutral pH (i.e., in DI water)*** . . . .”).

Conveniently, Avadel ignores these portions of the prosecution history and instead focuses on portions that (1) described the Liang formulations as capable of releasing “about 70%-100% of the drug within an hour at intestinal pH” and (2) characterized the claimed sustained release formulations as capable of “sustained release throughout the ileum and jejunum.” *Supra* at 12 (citing Ex. B at 9 and Ex. C at ¶¶ 6-7). The portions of the file history that Avadel relies on do not support its attempt to import a negative limitation and to exclude a pH-based intestinal *in vivo* release profile from the claims. *Purdue Pharma v. Endo Pharmaceuticals* is on-point and instructive. The patentee there told the Patent Office that its claimed formulation was distinguishable from the prior art because the patentee had “surprisingly discovered” that a four-fold range of dosages (10-40 mg) achieves the same clinical results as a prior art formulation using an eight-fold range (10-80 mg). *See* 438 F.3d 1123, 1126-27 (Fed. Cir. 2006). Based on this “discovery,” which overcame the obviousness rejection, the trial court construed the claims to be “limited to a four-fold dosage range that controls pain for 90% of patients.” *Id*. at 1135. The Federal Circuit reversed that construction because the patentee never clearly or unmistakably asserted that the four-fold range was a “necessary feature of the claimed oxycodone formulations.” *Id*. at 1136. Rather, the Federal Circuit held that, because the patentee had only touted the four-fold range as “a property of, or a result of administering, the oxycodone formulation characterized” by the limitations set forth in the body of the claims, there could be no finding of clear and

unmistakable disavowal. *Id.*; *accord Novartis Corp. v. Lupin Ltd.*, No. 06-5954, 2009 WL 737043, at *7 (D.N.J. Mar. 18, 2009) (no surrender of claim scope where patentee did not "clearly describe a single daily dose as a necessary feature of the [asserted] patent").

The same outcome is warranted here. Each asserted claim recites a specific DI water-based *in vitro* release profile and specific structural limitations for the sustained release coating. As set forth above, these are the two bases on which Jazz explained to the USPTO that the claimed inventions were patentable over Liang. As such, these are the necessary features of the claimed invention. Jazz never clearly and unmistakably asserted that not "releasing a majority of the drug within an hour upon exposure to intestinal pH" is also a necessary feature of its invention. As such, Jazz did not and could not have surrendered claim scope. At most, the portions of the file history that Avadel relies upon suggest that "sustained release throughout the ileum and jejunum" is a "result of administering" the claimed formulations; that result is not a claim limitation. *See Purdue*, 438 F.3d at 1136; *Celgene Corp. v. Hetero Labs Ltd.*, No. 17-3387, 2020 WL 3249117, at *7 (D.N.J. June 16, 2020) (declining to import limitation based on prosecution history where "the unexpected efficacious treatment of relapsed or refractory multiple myeloma with [the drug] was merely a 'result of administering' the claimed invention").

Avadel's cited cases are in agreement. In each, the patentee expressly argued for patentability on the basis of the limitation at issue. *See Omega Eng'g, Inc., v. Raytek Corp.*, 334 F.3d 1314, 1327 (Fed. Cir. 2003) (disclaimer where patentee "***repeatedly insisted*** that its invention differed from the prior art by precluding appreciable heat from entering the energy zone"); *SpeedTrack, Inc. v. Amazon.com*, 998 F.3d 1373, 1379-80 (Fed. Cir. 2021) (disclaimer where "patent applicants ***repeatedly highlighted*** predefined hierarchical field-and-value relationships as a difference between [the prior art] and the [asserted] patent"); *Sensormatic Electronics, LLC v.*

Genetec (USA) Inc., No. 20-760, D.I. 68, at 8 (D. Del. Sept. 29, 2021) (disclaimer where, following anticipation rejection, applicant amended claims and argued the added element was a "***required***" aspect of its invention); *Tech. Props. Ltd. LLC v. Huawei Techs. Co.*, 849 F.3d 1349, 1358 (Fed. Cir. 2017) (disclaimer where, "***[t]hroughout the prosecution history***, the patentee argued [that the prior art] was distinguishable for two specific reasons . . ."); *Transcend Med., Inc. v. Glaukos Corp.*, No. 13-830, 2015 WL 263612, at *7 (D. Del. Jan. 16, 2015) (disclaimer where applicants stated that the prior art featured "an *artificially created space* for aqueous drainage as opposed to a naturally occurring and existing physiologic outflow path as ***required*** by Applicants' claims"); *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, No. 20-985, 2022 WL 1026983, at *4 (D. Del. Apr. 6, 2022) (disclaimer where "***[t]hroughout the prosecution history***, the patentee makes clear that the claimed granules having the required bulk density are granules of the API alone").[9]

In contrast, here, Avadel relies upon part of a single response to an office action to support its efforts to limit the claims. Avadel ignores that the applicants never clearly and unambiguously stated that the negative *in vivo* release profile Avadel seeks to import was a required element of the claims; indeed, the applicants never clearly and unambiguously asserted the claims were patentable over Liang because of any *in vivo* release characteristics. Without clear, unmistakable language, the statements in the prosecution history on which Avadel relies are insufficient to import a negative claim limitation. *See Purdue*, 438 F.3d at 1136.

[9] *MBO Labs* (*supra* at 13) is inapposite, as the inquiry there was whether a preamble phrase should be limiting, not whether a limitation should be imported into the preamble phrase.

(2) The intrinsic and extrinsic evidence supports Jazz's proposal

Avadel argues that Jazz's proposed construction is at "odds with the repeated disclosures in the specification that refer to the invention as releasing over a prolonged period of time." *Supra* at 14. Avadel's argument stems from its misunderstanding of Jazz's construction, which Avadel views as "calculated to encompass *any* drug release profile modified in *any* way." *Id.*

As an initial matter, Jazz's construction would not "encompass *any* drug release profile modified in *any* way" for the simple reason that the claims themselves set forth parameters for the release profile of the invention. *See supra* at 7-8. Jazz therefore submits that "sustained release portion" should be construed in accordance with its plain and ordinary meaning, i.e., the portion of the formulation that is not immediate release and that releases over a period of time. That construction reflects the reality (as set forth in the intrinsic record) that different sustained release formulations may release over different periods of time. As the applicants explained, "[s]ustained release formulations . . . provide for a more gradual, but extended release of the drug over a period of time. Such a formulation could start releasing the drug shortly after dosing, or there could be a lag before the drug starts to release." *See* Ex. 2 at 8-9. Jazz's construction simply reflects the full scope of the claim term. Notably, Avadel does not provide any evidence contradicting the technical dictionaries showing that a POSA would understand "sustained release" to be a term of art having the plain meaning proposed by Jazz. *See, e.g.*, *supra* at 9-10; *id.* at Exs. 3-4.

d) Avadel's Sur-Reply Position

Avadel's proposal reflects Jazz's prosecution statements distinguishing its "sustained release" formulations from Liang's formulations, which Jazz argued release the "majority of the drug" "within an hour upon exposure to intestinal pH." *Supra* at 10-14. Jazz thus told the public:

- "The ***presently claimed invention*** is directed to an oxybate formulation with a ***sustained release*** component. Liang however, teaches a ***delayed release*** formulation." Ex. B at 8.

- "As [Liang's] 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.*** As shown in Example 7 and Figures 1 and 2 of Liang, these '***delayed release*** prototypes' ***release about 70%-100% of the drug within an hour at intestinal pH.***" *Id.* at 9.

- "[Liang's] pH sensitive coatings ***would release GHB relatively rapidly, i.e., in about an*** hour***, upon exposure to intestinal pH***." Ex. C at ¶ 6.

- "This ***sustained release formulation provides for a gradual, but extended release of GHB*** over a period of time." *Id.* at ¶ 3.

Jazz's attempts to cabin these clear and unambiguous statements are unavailing.

Jazz disclaimed claim scope: Avadel's proposal is based on Jazz's amendment from "controlled release" to "sustained release" ***and*** Jazz's arguments explaining what "sustained release" included. *Supra* at 10-13. Each constitutes disclaimer. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999) ("[I]t is irrelevant whether [patentee] relinquished this potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference."). That Jazz made other arguments does not avoid its disclaimer. *See supra* at 15-16.

Jazz's statements also have the requisite clarity: Jazz unambiguously argued that Liang's formulations "would release the majority of the drug relatively rapidly upon exposure to intestinal pH (e.g., about 6 and above), ***i.e., delayed release***." Jazz's use of "*i.e.*" defined Liang's "delayed release." *See Rembrandt Wireless Techs., LP v. Samsung Elecs. Co.*, 853 F.3d 1370, 1376 (Fed. Cir. 2017) (finding use of "i.e." during prosecution to be definitional); *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009) ("[U]se of 'i.e.' signals an intent to define the word to which it refers."). And after defining Liang's "delayed release," Jazz argued that its "sustained release" formulations were distinct; *e.g.*: "The ***presently claimed invention*** is directed

to an oxybate formulation with a ***sustained release*** component. Liang however, teaches a ***delayed release*** formulation." Ex. B at 8. Such clear statements rise to the level of disclaimer. *Supra* at 10-14.

Jazz's objections that "intestinal pH" is improperly based on an *in vivo* release profile again ignores that Avadel's proposed construction comes *directly* from Jazz's prosecution arguments:

> As [Liang's] 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***. As shown in Example 7 and ***Figures 1 and 2 of Liang***, these "*delayed release* prototypes" release *about 70%-100% of the drug within an hour* ***at intestinal pH***.

Ex. B at 9. Avadel's construction simply reflects how Jazz distinguished Liang's "delayed release" from its "sustained release," regardless of whether Jazz characterized it as *in vitro* or *in vivo* release.

Jazz's legal authorities do not support it: *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123 (Fed. Cir. 2006), does not hold that prosecution statements about the "results" of the claims can never create disclaimer.[10] *Supra* at 19-21. In *Purdue*, the Federal Circuit explained that there was no disclaimer of formulations that did not control pain in approximately 90% of patients because the "claims contain no [efficacy] limitations" and efficacy was not a "necessary feature" of the claimed formulations. 438 F.3d at 1136. Thus, the only way the trial court could find disclaimer "was to state that the 'invention itself'" required the result, which would "impermissibly import[] a limitation into the claims." *Id.* at 1136-37 (citation omitted). At most,

[10] Jazz's other citations likewise fail. *See Celgene Corp. v. Hetero Labs Ltd.*, C.A. No. 17-3387-ES-MAH, 2020 WL 3249117, at *5 (D.N.J. June 16, 2020) (rejecting disclaimer based solely on the *preamble* language to "treating multiple myeloma"); *Novartis Corp. v. Lupin Ltd.*, Civ. No. 06-5954 (HAA)(ES), 2009 WL 737043, at *7 (D.N.J. Mar. 18, 2009) (finding that prosecution statements "permitting, but not mandating, a single dose" did not rise to the level of disclaimer").

Purdue stands for the unremarkable proposition that "statements or disavowals must directly address the disputed term" to limit claim scope. *Sky Techs., LLC v. Ariba, Inc.*, 491 F. Supp. 2d 154, 156 (D. Mass. 2007).

Here, Jazz repeatedly tied its arguments to the "sustained release" limitation. *See, e.g.*, Ex. B at 8; Ex. C at ¶ 3. In doing so, Jazz clearly distinguished "sustained release" from what it defined as Liang's "delayed release" formulations. Ex. B at 9; Ex. C at ¶ 6. A POSA would understand from these statements that "sustained release" does not include what Jazz called "delayed release." *See Acadia Pharms. Inc. v. Aurobindo Pharma Ltd*, C.A. No. 20-985-RGA, 2022 WL 1026983, at *2-5 (D. Del. April 6, 2022) (limiting "pimavanserin tartrate" to granulation alone because of patentee's statements about the "surprising" results from granulating alone, to distinguish prior art).

2. "By about 4 to about 6 hours"

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
"by about 4 to about 6 hours"	Plain and ordinary meaning, i.e., by approximately 4 to approximately 6 hours	Plain and ordinary meaning, which is at any point prior to about 4 hours or at any point prior to about 6 hours

a) Jazz's Opening Position

As set forth above, the claims of the Sustained Release Patents expressly set forth the specific dissolution profile, in the specific media, that any "sustained release portion" of the claimed formulation must have: "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 . . . ." The parties dispute the meaning of "by about 4 to about 6 hours."

While both parties purport to propose the plain and ordinary meaning for this term, only Jazz's proposal is consistent with the plain and ordinary meaning of "about." It is well settled that

"[t]he use of the word 'about,' avoids a strict numerical boundary to the specified parameter." *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995). To that end, the Federal Circuit has repeatedly held that the plain and ordinary meaning of "about" is "approximately." *See Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372–73 (Fed. Cir. 2005); *Par Pharm., Inc. v. Hospira, Inc.*, 835 F. App'x 578, 581 (Fed. Cir. 2020).

Avadel's proposal, on other hand, seeks to read the phrase "prior to" into the claims without any support in the claims, specification, or file history. This is improper. *See, e.g.*, *Home Semiconductor*, 701 F. App'x at 1011. Accordingly, the Court should reject Avadel's proposed construction.

b) Avadel's Answering Position

Jazz's proposed construction of "by about 4 to about 6 hours" does not resolve the parties' apparent dispute as to the word "by." "By" should be given meaning; "[c]laims are interpreted with an eye toward giving effect to all terms in the claim." *Enzo Biochem Inc. v. Applera Corp.*, 780 F.3d 1149, 1154 (Fed. Cir. 2015) (citation omitted). "By" has an ordinary meaning of "not later than," (*see* CAMBRIDGE DICTIONARY OF AMERICAN ENGLISH (1st ed. 2000) at 112 (definition of "by") (attached as Ex. E)), and should be given that meaning. Jazz ignores the term "by" and, by suggesting some amorphous "plain meaning," does not resolve the parties' dispute. *Eon Corp. IP Holdings LLC v. Silver Spring Network, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016).

Absent intrinsic evidence giving the term a special meaning, Jazz should be held to the plain meaning. *See Free Stream Media Corp. v. Alphonso, Inc.*, 996 F.3d 1355, 1367 (Fed. Cir. 2021) ("Claim construction requires a determination as to how a person of ordinary skill in the art would understand a claim term 'in the context of the entire patent, including the specification.'") (internal citation omitted). The plain meaning of by ("not later than") means the term encompasses periods before "about 4 to about 6 hours," including, *e.g.*, 15 minutes, 1 hour, etc.

c) Jazz's Reply Position

Avadel's proposal for this term improperly reads "about" out of the claims. In accordance with Federal Circuit precedent (which Avadel does not address), Jazz proposes that "by about 4 to about 6 hours" be construed as "by approximately 4 to approximately 6 hours." *See Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("The use of the word 'about,' avoids a strict numerical boundary to the specified parameter."). Jazz's proposed construction therefore includes times that occur by approximately 4 hours to approximately 6 hours. In other words, there is no hard and fast cut-off at 4 or 6 hours, as Avadel proposes.

Avadel contends that "[t]he plain meaning of by ('not later than') means the term encompasses periods before 'about 4 to about 6 hours,' including, e.g., 15 minutes, 1 hour, etc." *Supra* at 26. But under Avadel's proposal, if "by about 4 to about 6 hours" is limited to times "before" and "not later than" 6 hours, then the word "about" is read out of the claims because times occurring after 6 hours would be excluded. Avadel cannot point to anything that would support reading the term "about" out of the claims. "Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). Avadel's proposal should, therefore, be rejected.

d) Avadel's Sur-Reply Position

The parties agree that "about" means "approximately." The only dispute (which Jazz ducks) is what "by" means: whether the claim covers any time before approximately 4 and approximately 6 hours (which is what it says) or whether it only covers a time ***between*** approximately 4 and approximately 6 hours (which Jazz may argue to narrow the claim). The ordinary meaning of "by" is "not later than." Avadel's construction should be adopted to avoid future mischief.

B. The '079 and '782 patents

1. "Controlled release component"

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
"controlled release component"	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

a) Jazz's Opening Position

Claim 1 of the '079 patent (Ex. 5) states (with emphasis on the disputed claim term):

> 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**.

The parties appear to agree that lexicography governs the construction of "controlled release component." The parties diverge, however, on what that proper lexicography is.

The relevant portion of the specification states:

> 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, or about 4 to 6 hours, including about 2, about 2.5, about 3, about 3.5, about 4, about 4.5, about 5, about 5.5, about 6, about 6.5, about 7, about 7.5, or about 8 hours, inclusive of all ranges therebetween. The release profile may be assessed using in vitro dissolution assays known to those of skill in the art, e.g., USP apparatus 2 (paddle) or, more preferably, apparatus 4 (flow-through cell). Particularly when the molar dose of oxybate is large and approaches the amount of anion in the dissolution media, a flow-through apparatus is desired so that the media

> composition and flow rate can better approximate the physiologic state. The release profile can be assessed for example (e.g., for bioavailability determinations), in pharmacokinetic studies using plasma concentrations to assess maximum concentration (C_{max}) and area under the curve (AUC). Such assays are well known to those of skill in the art.

See Ex. 5 at 6:55-7:8 (emphasis added).

Both parties agree that the inventors defined "controlled release" as "having a release over a period of at least about 2 to about 8 hours." Jazz submits that is the extent of the lexicography and all that is ***required*** by the "controlled release component" claim language. Avadel, on other hand, seeks to alter the lexicography to also include the expressly identified "***example*** GHB resinate compositions," which is shown underlined above, as part of the definition of "controlled release component."

Consistent with the use of the word "***example***" in the '079 patent's specification, controlled release formulations ***can be, but need not be,*** formulated from resins. Ion exchange resins are polymers that have the ability to exchange ions (charged particles) within aqueous solutions surrounding them. *See* Srikanth et al., *Ion-Exchange Resins as Controlled Drug Delivery Carriers*, J. SCI. RES., 2(3):597-611 (2010) (Ex. 6) at 598.[11] Complexes between ion exchange resins and drug substances may be formed, which are known as resinate compositions. *Id*. Resinate compositions may be utilized to create controlled release dosage forms, *see id.* at 603, but controlled release may also be achieved through various other formulation techniques.

Nothing in the intrinsic record requires that the controlled release component of Jazz's inventions be formulated as resinate compositions. Instead, the lexicography expressly states that resinates are an "example" of the claimed component. The resinate composition "example" is not

[11] Srikanth et al. was "incorporated by reference" in its entirety into the specification of the '079 patent. *See* Ex. 5 at 3:4-18.

definitional for "controlled release," nor is it a disavowal of non-resinate compositions. S*ee, e.g.*, *Purdue Pharma L.P. v. Acura Pharms., Inc.*, 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."). And the Federal Circuit "has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification." *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986); *accord Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1371 (Fed. Cir. 2009).

Accordingly, this Court should adopt the agreed-upon language that a controlled release component comprises an active pharmaceutical ingredient having a release over a period of at least about 2 to about 8 hours, and reject Avadel's unsupported attempt to alter the lexicography and limit the claims to an "example" in the specification.

b) Avadel's Answering Position

The parties dispute whether "controlled release component" can encompass *any* pharmaceutical composition that achieves controlled release, as Jazz proposes, or whether it should be limited to compositions that achieve controlled release using ion-exchange resins (also known as resinates), as Avadel proposes. Avadel's proposal most naturally aligns with the specification's descriptions of the "present invention" and should be adopted.

The parties agree that the '079 patent includes a lexicographic definition for "controlled release": "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 . . . . inclusive of all ranges therebetween." '079 patent at 6:55-63. The disagreement lies in how a POSA would understand that definition.

A POSA reviewing the specification would understand that the claimed invention is

directed to resinate compounds that allow for "controlled release" of a drug substance. The specification repeatedly makes clear that "the present invention" is limited to resinate dosage forms. For instance, the specification provides examples of desired drug release characteristics and explains that "[f]ormulation of such drugs *as resinates according to the present invention* permits particles sizes that make such release characteristics feasible . . . ." *Id.* at 15:13-16. The inventors also assert that "the unusually high molar doses of GHB *of the resinate compositions of the present invention*" can prevent "mucoadhesion" (*i.e.*, the binding of particles together), a problem found in prior art, microparticle compositions. *Id*. at 21:25-30. Elsewhere, the specification notes that "supplemental anions can be coadministered with the oxybate compositions of the present invention, for example within about an hour (before or after) of administering *the drug resinate (e.g. oxybate resinate) compositions of the present invention*, or simultaneously therewith." *Id.* at 20:62-66. And the specification explains that "[a]ny anion exchange suitable for pharmaceutical use can be employed *in the compositions of the present invention*, particularly strong anion exchange resins." *Id.* at 8:33-35.

Moreover, the specification explicitly and repeatedly disparages non-resinate controlled release mechanisms and distinguishes them from "the present invention." The inventors explain:

> The solubility of sodium oxybate is unusually high. For example, a Xyrem solution is provided as 500 mg/mL concentration in water, or 42 wt%, and its solubility limit is considerably higher. Furthermore, due to the small size and ionic nature of GHB at physiological pH, the drug is unusually mobile in solution. Those skilled in the art will appreciate that *these factors* complicate and, in many cases, *limit conventional approaches for modified release, such as core/shell or matrix formulations*, as the high solubility and mobility of GHB would tend to *significantly reduce the number of viable approaches using such conventional solubility and diffusivity control technologies.*

Id. at 5:49-60; *see also id*. at 6:1-4 (explaining that "matrix and coating compositions" are

"complex and expensive to produce."). The specification then asserts that "[a] drug-resin complex may address some of these limitations, as the drug is essentially insoluble as long as it remains bound to the resin." *Id.* at 6:12-14. Finally, every single "controlled release" composition disclosed in the specification is a resinate composition. *See, e.g.*, *id.* at 22:28-30, 22:51-52, 23:22, 23:52-54, and 23:67-24:1.

Despite the specification's consistent focus on resinate formulations, Jazz argues that the phrase "GHB resinate compositions as described herein" in the definition of "controlled release" means that such formulations "can be, but need not be, formulated from resins," because it follows the words "for example." *Supra* at 29-30. But a lexicographic definition should not be read in isolation, and the proper construction must be interpreted according to the specification as a whole. *See Cirba Inc. v. VMware, Inc.*, C.A. No. 19-742-LPS, D.I. 1160 at 11 (D. Del. Feb. 24, 2022) (construing a disputed claim term more narrowly than the lexicographic definition in the specification based on other disclosures in the specification that were "consistent with the express definition while providing more specificity") (attached as Ex. F); *see also Gemalto S.A.*, 754 F.3d at 1369 (quoting *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1340 (Fed. Cir. 2006) ("Of course, 'the claims cannot be of broader scope than the invention that is set forth in the specification.'")). Here, the specification describes resinate compositions that do not contain *GHB*—supporting that it is the "GHB" portion of "GHB resinate compositions" that is exemplary. In contrast, every example describes, or relates to, resinates, indicating that the "resinate" portion of that phrase is *not* exemplary. *Compare* '079 patent at 8:24-32 (identifying various drugs in addition to GHB for use in "ion-exchange resins") *with id.* at 22:24-24:55 (Examples 1-7).

These disclosures, and in particular, the specification's repeated descriptions of the "present invention" shed light on how "one of ordinary skill in the art reading the specification

would have understood" the claim term. *See, e.g.*, *Secure Web Conference Corp. v. Microsoft Corp.*, 640 Fed. App'x 910, 914 (Fed. Cir. 2016) (holding that a POSA would have "understood" a "security device" to be "limited to a stand-alone device" based "particularly" on a description of the "present invention."). Based on the specification's repeated description of the "present invention" as a resinate composition, a POSA would understand the specification's definition of "controlled release" to be restricted to resinates, particularly given the specification's disparagement of non-resinate controlled release formulations.

Moreover, the specific phrase "according to the present invention" has been repeatedly held to characterize the invention as a whole. *See Secure Web Conference Corp.*, 640 Fed. App'x at 914-15 (holding that a figure showing "a communication system according to the present invention" depicted "the essence of the claimed invention rather than a preferred embodiment"); *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 629 F.3d 1311, 1326-27 (Fed. Cir. 2010), *vacated on other grounds sub nom*, *Akamai Techs., Inc. v. MIT*, 419 Fed. App'x 989 (Fed. Cir. 2011) (*en banc*); *Gaus v. Conair Corp.*, 363 F.3d. 1284, 1290 (Fed. Cir. 2004) (holding that accomplishing a function "according to the invention" demonstrated what "the invention itself requires"). Jazz used that precise phrase throughout the specification, including by stating explicitly that: "[f]ormulation of such drugs *as resinates according to the present invention* . . . make such release characteristics feasible . . . ." '079 patent at 15:13-16.

The foregoing statements describing the "present invention" and disparaging non-resinate formulation themselves are sufficient to show that, based on the intrinsic evidence as a whole, a POSA would have understood "controlled release" as limited to resinate formulations. Nevertheless, those same statements also disavow non-resinate formulations. Specifically, the Federal Circuit has held that "present invention" statements disavow claim scope because they

"teach[] that the present invention solved a particular problem in the prior art . . . with a specific feature . . . ." *Campbell Soup Co. v. Gamon Plus, Inc.*, No. 2020-2322, 2021 WL 3671366 at *4 (Fed. Cir. Aug. 19, 2021).[12] Similarly, the Federal Circuit has recognized, "an inventor may disavow claims lacking a particular feature when the specification distinguishes or disparages prior art based on the absence of that feature." *See Poly-America*, 839 F.3d at 1136.

The Federal Circuit's *Level Sleep LLC v. Sleep Number Corp*. decision regarding disclaimer, disparagement, and lexicography is instructive. The patent-in-suit defined "low body pressure," as "a pressure [applied by a bed on the sleeper] which is below a pressure threshold (typically the ischemic threshold) for comfortable sleep. . . ." No. 2020-1718, 2021 WL 2934816 at *1 (Fed. Cir. July 13, 2021). The specification explained that ischemic threshold was about 30 mmHg and that a "conventional mattress" applied 40 or 80 mmHg of pressure. *Id.* at *1-2. By disparaging the prior art, the inventors disavowed claim scope and narrowed the definition to pressures "at least below 40 mmHg." *Id.* at *5. Notably, the Court applied the disclaimer without limiting the definition to the exemplary language in the definition that the "pressure threshold" was "typically the ischemic threshold" of 30 mmHg. *Id.* at *4-5.

The '079 patent presents a stronger case for disclaimer than *Level Sleep* for two reasons. First, the specification includes examples of compounds in addition to GHB (like GBL) that can be included in the compositions of the invention, giving meaning to the "for example" language. Indeed, the '079 patent even uses oxybate resinates as an exemplary drug resinate in describing "the drug resinate (e.g. oxybate resinate) compositions of the present invention." '079 patent at 20:62-66. Second, as discussed above, the '079 patent both describes resinate formulations as the

[12] *See also Poly-America, L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016) ("[A]n inventor may disavow claims lacking a particular feature when the specification describes 'the present invention' as having that feature.") (citation omitted)).

"present invention" and disparages "conventional" non-resinate technologies.

c) Jazz's Reply Position

Avadel argues that this term should be limited to "resinate compounds that allow for 'controlled release' of a drug substance," because "[t]he specification repeatedly makes clear that 'the present invention' is limited to resinate dosage forms." *Supra* at 31.

Avadel is wrong. The specification describes numerous embodiments of "the present invention" without ever mentioning, let alone limiting the claims to, resinate compositions. *See* Ex. 5, '079 Patent at 4:35-38 ("In one embodiment, the present invention is directed to formulations of drugs that are carboxylic acids, as described herein, and are suited to the controlled release of high dose drugs that are highly water soluble."), 6:42-45 ("In one embodiment, 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 as described herein."), 13:9-12 (describing another embodiment of "the present invention" not limited to resinate compositions), 13:32-39 (same) 13:57-65 (same), 13:66-14:2 (same), 18:62-66 (same). Thus, while ***some embodiments*** may be accomplished through the use of resinate compositions, that is not a necessary component of the claimed inventions.

This is consistent with the lexicography, which expressly states that resinate compositions are "example[s]" of controlled release compositions. *Id.* at 6:55-7:8. Avadel recognizes this lexicography, but argues that it is only "the 'GHB' portion of the 'GHB resinate compositions' that is exemplary." *Supra* at 32. But the definition says that "'controlled release' refers to compositions, for example GHB resinate compositions," not that controlled release ***refers to resinate compositions, for example of GHB***. *See* Ex. 5, '079 Patent at 6:55-7:8. And the specification makes clear that resinate compositions are just one example of the oxybate (i.e., GHB) compositions of the "the present invention." *Id.* at 21:35-38 ("The oxybate compositions

of the present invention, ***for example oxybate resinate compositions***, provide therapeutically effective levels of oxybate over a period of at least about 3 to about 8 hours."). Avadel's attempt to rewrite the lexicography is improper.

Moreover, the description of exemplary embodiments as the "present invention" does not permit limiting claim scope. *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"); *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358 (Fed. Cir. 2016) ("It is not true that because one sentence in the paragraph begins with the 'present invention' language that everything that follows in the same paragraph limits all subsequent claims."); *Corcept Therapeutics, Inc. v. Teva Pharm. USA, Inc.*, No. 18-3632, 2020 WL 3425302, *3-4 (D.N.J. 2020) (holding "the present invention" did not limit claim where "the specification contains other descriptions of the 'present invention' that do not include the [proposed limitation]").

Avadel's cited cases are in agreement; each found disavowal because the specification's description of the "present invention" ***uniformly*** used limiting language. As the Federal Circuit explained in *Campbell Soup Co. v. Gamon Plus, Inc*., statements describing the "present invention" do "not amount to disavowal where the specification does not uniformly require the limiting feature." No. 20-2322, 2021 WL 3671366, at *5 (Fed. Cir. Aug. 19, 2021). Thus, Avadel's cases are all readily distinguishable because—unlike here—the specifications' descriptions of the "present invention[s]" were uniform. *See Secure Web Conference Corp. v. Microsoft Corp.*, 640 F. App'x 910, 914 (Fed. Cir. 2016) (disavowal where specification "***never once suggests*** embedding the security device within the microprocessor-based device"); *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 629 F.3d 1311, 1327 (Fed. Cir. 2010) (disavowal where

"the specification as a whole makes clear that including the object's original URL is ***the only method*** to achieve the claimed association between an alphanumeric string and the embedded object"); *Gaus v. Conair Corp.*, 363 F.3d. 1284, 1288 (Fed. Cir. 2004) (finding claim directed to shock prevention device must include a probe network that is "separate and operates independently from any voltage carrying part of the apparatus" because "***nothing in the descriptions*** of those two components suggests that their structures or functions overlap"); *Poly-Am., L.P. v. API Indus., Inc.*, 839 F.3d 1131 (Fed. Cir. 2016) (disavowal where "***[e]very embodiment*** described in the specification has inwardly extended short seals").

Level Sleep LLC v. Sleep Number Corp., which Avadel argues is particularly "instructive" (*see supra* at 34), also fails to support Avadel's position. There, since the specification defined "pressure threshold" as "below the ischemic pressure of about 30 mmHg," the Federal Circuit limited the claims as such because where "a patent applicant has elected to be a lexicographer by providing an explicit definition in the specification for a claim term," the "definition selected by the applicant controls." No. 2020-1718, 2021 WL 2934816, at *4 (Fed. Cir. July 13, 2021). As explained above, there is no such limiting lexicography for "controlled release."[13]

Avadel further argues that the specification allegedly disparages non-resinate GHB formulations. *See supra* at 31-32. But the cited portions of the specification do not limit the claims to resinate compositions; instead, they focus on difficulties with the long-term storage of

[13] *Cirba* (*supra* at 32) also does not support limiting the lexicography here. There, the specification contained a terse definition for source system: "a system from which applications and/or data are to be moved." The parties disputed whether the term "encompasses physical, virtual, or hypothetical systems," a question not answered by the lexicography. The court construed the term to include physical, virtual, or hypothetical systems, noting it could not identify "examples of systems that may be improperly excluded under [the construction]." In other words, the Court did not narrow the lexicography, but only clarified what it could include.

liquid controlled release formulations and why solid sachet formulations (such as those claimed in the '079 patent) would be preferable. Controlled release formulation methods that are relevant for non-claimed liquid formulations, even if they were limited to resinate compositions (they are not), are not relevant to the claimed sachet formulations.[14] Thus, Avadel's argument fails.

d) Avadel's Sur-Reply Position

The specification repeatedly characterizes the "present invention" as a "resinate" composition. *See supra* at 30-32; '079 patent at 9:6-8 ("For the oxybate resinate compositions of the ***present invention***, the amount of oxybate present ***in the resinate*** should be high . . . .").

Jazz cites a handful of disclosures not reciting resinates. Critically, none disclose ***non***-resinate formulations, but instead address other characteristics of the "present invention" resinate formulation. For example, the disclosure that the "invention is directed to formulations of drugs that are carboxylic acids, as described herein and are suited to the controlled release of high dose drugs that are highly water soluble," '079 patent at 4:35-38, describes the drug in the resinate, such as GHB, which the specification teaches is a carboxylic acid. *See id.* at 5:29-30. Similarly, disclosures that "the present invention provides a GHB formulation which delivers a controlled release profile," *id.* at 6:42-45, and that "the present formulation is administered to a patient once nightly," *id.* at 18:62-66, describe the desired functionality of the claimed invention and are consistent with the claimed formulations being resinates. So too the disclosures that the formulation can include excipients such as "at least one binder," *id.* at 13:12-21, "one or more lubricants," *id.* at 13:32-39, "colorants" and "flavoring agents," *id.* at 13:57-65, or "pH adjusting

[14] In *Gemalto (supra* at 32*)*, the claims covered "integrated circuit cards" that contained both a CPU and memory. The court held the claims could not cover the defendants' circuit cards—which did not contain both a CPU and memory—because the specification's only discussion of such disjointed technology was when disparaging the prior art. The specification here does not disparage methods of administering non-resinate formulations from a sachet and, thus, *Gemalto* does not support Avadel's position.

or buffering agent[s]," *id.* at 13:66-14:2. Such descriptions of other aspects of the "present invention" do not contradict the numerous teachings limiting the "present invention" to resinate formulations. *See Techtronic Indus. Co. v. Int'l Trade Comm'n*, 944 F.3d 901, 907-08 (Fed. Cir. 2019) (patent "consistently represent[ed] the invention as the placement of the detector in the wall console," even where specification "describe[d] the invention more broadly as 'relat[ing] in general to movable barrier operators'"); *Rsch. Frontiers, Inc. v. E Ink Corp.*, C.A. No. 13-1231-LPS, 2016 WL 1169580, at *5 n.10 (D. Del. Mar. 24, 2016), *report and recommendation adopted*, C.A. No. 13-1231-LPS, 2016 WL 7217217 (D. Del. Dec. 13, 2016), *aff'd*, 706 F. App'x 685 (Fed. Cir. 2017) (restricting element to "controls light transmission" where description of "other aspects of the 'present invention' that do not directly discuss the concept of controlling light transmission" did not "expressly contradict[] the patent's earlier reference to the invention's control of light transmission").

Jazz's cases all address instances where the specification lacked uniform disclosures of the "present invention" with respect to the disputed term. In *Continental Cirs. LLC v. Intel Corp.*, the court declined to limit the claims to the repeated desmear process that the specification only taught was "a way" of manufacturing the claimed invention without "uniformly requir[ing]" its use. 915 F.3d 788, 797 (Fed. Cir. 2019). In *Unwired Planet, LLC v. Apple Inc.*, the court declined to limit the claimed invention to a "voice channel" where it was unclear that the single "present invention" statement applied to voice channels. 829 F.3d 1353, 1358 (Fed. Cir. 2016). And in *Corcept Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, the specification "lack[ed] the clear manifestation required to exclude or restrict the claims," in light of "present invention" statements that identified alternatives to the proposed limitation. C.A. No. 18-3632 (SDW) (LDW), 2020 WL 3425302, at *3 (D.N.J. June 23, 2020). No such inconsistencies exist in the '079 patent. *See supra* at 30-35.

Jazz's lexicography arguments concerning "controlled release compositions" likewise fail. As Jazz's Responsive Brief concedes, *see supra* at 14-15, the patent describes the use of *drug substances* other than GHB. A POSA would thus understand the exemplary language in the definition of "controlled release" to refer to different drugs that can be formulated as resinates. And the disclosure that "[t]he oxybate compositions of the present invention, for example oxybate resinate compositions, provide therapeutically effective levels of oxybate ***over a period of at least about 3 to about 8 hours***," '079 patent at 21:35-38, is consistent with the disclosures that ***controlled release*** *components* are resinates, while immediate release components can include non-resinate forms.

2. "Modified release particles"

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
"modified release particles"	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

a) Jazz's Opening Position

Claim 1 of the '782 patent (Ex. 7) states (with emphasis on the disputed claim term):

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**.

Both the intrinsic record and extrinsic evidence support Jazz's construction.

(1) The intrinsic record supports Jazz's construction

Modified release particles have a release profile that is different from that of an immediate release particle. In other words, and as the Examiner stated during prosecution of the '782 patent, "modified release portion is broadly interpreted as being modified in some way." *See* Ex. 8 at 5-6. "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." *Salazar v. Procter & Gamble Co.*, 414 F.3d 1342, 1347 (Fed. Cir. 2005). That is the case here.

Nothing in the intrinsic record supports reading Avadel's two proposed limitations—(1) that the GHB release "over a period of about 2 to about 8 hours;" and (2) that the formulation be a "resinate composition"—into the claims. Unlike for "controlled release component," there is no lexicography for "modified release particles" that would warrant inclusion of the "about 2 to about 8 hour" time period within the meaning of that phrase. And as explained above, there is no lexicography or disavowal that would permit (let alone require) the Court to limit the "controlled release component" or the "modified release particles," to the expressly identified "example" resinate compositions in the specification. "Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004)). For at least this reason, the Court should adopt Jazz's proposed construction.

(2) The extrinsic evidence supports Jazz's construction

The Court should also adopt Jazz's construction because it is the plain and ordinary meaning of the term, as further demonstrated by extrinsic evidence.

At the time of filing (and today), "modified release" was a term of art with a meaning readily understood by a POSA: a release profile that is different from that of an immediate release product. *See, e.g.*, 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."). Notably, courts have construed the term consistent with this plain and ordinary meaning. For instance, courts have held that the plain and ordinary meaning of a "modified release material" is "a material that modifies the release of the active pharmaceutical ingredient." *See Ferring B.V. v. Mylan Pharms. Inc.*, No. 13-5909, 2014 WL 6676670, at *3 (E.D. Pa. Nov. 25, 2014); *see also, e.g.*, *Warner Chilcott Labs Ireland v. Impax Labs., Inc.*, No. 08-06304, 2011 WL 2971155, at *3 (D.N.J. July 20, 2011) (construing "modified release preparation" as "preparation that provides a release profile for an active ingredient that is different from that of an immediate release preparation").

Accordingly, this Court should adopt Jazz's construction of "modified release particles," and reject Avadel's attempt to import two unsupported limitations into the claims.

b) Avadel's Answering Position

"Modified release particles" should be construed consistent with the term "controlled release component" previously discussed. Although the terms are different, the Resinate Patents use them interchangeably. Courts have recognized that where the patentee uses two terms interchangeably, they should be construed to have the same meaning. *Leader Techs, Inc. v. Facebook, Inc.*, 692 F. Supp. 2d 425, 429 (D. Del. 2010) (construing "context" and "environment" to have the same meaning where they were "used interchangeably" by the applicant). Here, "modified release" appears only twice in the specification. The specification initially uses the term to describe formulation challenges associated with sodium oxybate's solubility: "[t]hose skilled in the art will appreciate that these factors complicate and, in many cases, limit conventional

approaches for *modified release*, such as core/shell or matrix formulations . . . ." '782 patent at 5:55-58. The patent then identifies drug-resin complexes as a potential solution to these issues and states that "[d]rug-resin complexes including *modified release* drug-resin complexes are known." *Id.* at 6:21-22. That discussion continues, describing specific resinate types and the "*controlled release* profile" that "the present invention provides." '782 patent at 6:43-44. The patent therefore draws no distinction between "modified" and "controlled" release. The passage then culminates in the definition of "controlled release." '782 patent at 6:56-64. Thus, the patent uses controlled release and modified release interchangeably.

Jazz ignores the specification and cites a lone statement from the Examiner that "modified release portion is broadly interpreted as being modified in some way" in an effort to give "modified release" a different meaning than "controlled release." *Supra* at 41, Ex. 8 at 5-6. That statement does not support Jazz's assertions. The Examiner was simply confirming that "*controlled release* in the prior art *reads on the limitation* of *modified release* in the instant claims." Ex. 8 at 6. Moreover, the Examiner's construction reflects the application of the "broadest reasonable interpretation" standard for claim interpretation used during prosecution. But the Manual of Patent Examining Procedure explicitly cautions that "[p]atented claims are not given the broadest reasonable interpretation during court proceedings involving infringement and validity and can be interpreted based on a fully developed prosecution record." Manual of Patent Examining Procedures § 2111. As such, courts have rejected efforts to import constructions under that broad standard into litigation. *Groove Digital, Inc. v. United Bank,* 825 F. App'x 852, 857 n.5 (Fed. Cir. 2020).

Further, to the extent the Office Action should be considered, as Jazz asserts, it provides additional evidence that "modified release" is used interchangeably with "controlled release" in

the Resinate Patents. There, the Examiner cited a portion of the specification describing "controlled or extended release" as providing written description support for a "modified release" formulation, demonstrating its understanding that "modified release" was used interchangeably with "controlled or extended release." Ex. 8 at 3. Based on this, the intrinsic evidence is clear. There is no need to resort to extrinsic evidence as Jazz proposes, and no justification for construing "modified release" as having a different scope than "controlled release."

Even if the intrinsic record did not use "modified release" and "controlled release" interchangeably, a POSA would understand from the specification's descriptions of the "present invention" and disparagement of non-resinate formulations that "modified release particles" were limited to resinates. *See supra* at III.B.1.b). Indeed, the only two uses of "modified release" in the entire specification appear in the passage discussing the improvements of the disclosed formulations, alleging that "[a] drug-resin complex may address some of the[] limitations" of "conventional approaches." '782 patent at 5:50-6:20. Thus, any construction of "modified release particles" should be limited to resinates, as Avadel proposes.

c) Jazz's Reply Position

Avadel asserts that "modified release particles" should be construed the same as "controlled release component" because the '079 Patent and the '782 Patent allegedly "use them interchangeably." *Supra* at 42. According to Avadel, the specification "draws no distinction between 'modified' and 'controlled' release." *Id.* Avadel's argument overlooks two key facts: (1) "controlled release" is expressly defined in the shared specification, and (2) "modified release" is a broader term of art that a POSA would readily understand to include any release profile that is different from immediate release. *See supra* at 42 (citing, e.g., Ex. 9 at 4). The specification therefore does not need to expressly draw a distinction between the two terms, because one is defined and the other has a well-understood plain meaning. *See also Xmtt, Inc. v.*

Intel Corp., No. 18-1810, 2020 WL 2404825, at *3 (D. Del. May 12, 2020) (rejecting "the notion that two different terms can properly be construed to have the same meaning when used interchangeably throughout the specification and claims of a patent" where "the two are never 'conflate[d]' in the same sentence").

Avadel argues that, "[e]ven if the intrinsic record did not use 'modified release' and 'controlled release' interchangeably, a POSA would understand from the specification's descriptions of the 'present invention' and disparagement of non-resinate formulations that 'modified release particles' were limited to resinates." *Supra* at 44. But as set forth above and in Jazz's Opening Brief, a POSA would understand that resinate formulations were merely examples of the claimed modified release formulations.

Moreover, a POSA would have understood "modified release" to broadly refer to any drug release profile that is modified in some way. Indeed, the Examiner of the '782 Patent had that same understanding. *See supra* at 41. Avadel argues that the Court should ignore the Examiner's understanding. *See id.* at 43-44. But because an Examiner "can be considered one of ordinary skill in the art, his construction of the asserted claims carries significant weight." *St. Clair Intell. Prop. Consultants, Inc. v. Canon Inc.*, 412 F. App'x 270, 276 (Fed. Cir. 2011).

d) Avadel's Sur-Reply Position

Jazz contends that because the patent defines "controlled release component" and "modified release particles" is allegedly a term of art, the specification need not distinguish between the two. *See supra* at 44. That misses the point; the specification's interchangeable use of the terms—and the absence of any distinction between them—demonstrates that they have the same meaning.

Jazz cites *Xmtt, Inc. v. Intel Corp.*, in which the terms at issue were "never 'conflate[d]' in the same sentence." C.A. No. 18-cv-1810-RGA, 2020 WL 2404825, at *3 (D. Del. May 12, 2020).

The *Xmtt* court made this point only to distinguish *Wasica Finance GmbH v. Continental Automotive Sys., Inc.*, 853 F.3d 1272, 1282 n.6 (Fed. Cir. 2017). The Federal Circuit has never held that terms must be used interchangeably in the same sentence in order to define the same subject matter. Rather, the use of terms interchangeably in the specification is sufficient. *See HZNP Medicines LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 698 (Fed. Cir. 2019) (terms should be defined the same when used interchangeably); *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010) (implication that different terms have different meanings is overcome when "the evidence indicates that the patentee used the two terms interchangeably").

Finally, Jazz contends that the Examiner's views on claim construction should be accorded significant weight. *Supra* at 45. But as Avadel explained, Jazz misapplies the Examiner's statement and, in any event, the Examiner was applying a different standard. *Supra* at 43.

C. REMS Patent

1. Whether the REMS Patent claims systems or methods

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
A computer-implemented system for treatment of a narcoleptic patient with a prescription drug that has a potential for misuse, abuse or diversion	The '963 patent claims methods of using a computer-implemented system to safely distribute gammahydroxybutyrate for treatment of a narcoleptic patient	The claims are directed to systems and not to methods

a) Jazz's Opening Position

The parties dispute four terms, emphasized in claim 1 below, in the REMS Patent (Ex. 10).

> 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;
>
> 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**.

Avadel argues that the REMS Patent's "claims are directed to systems and not to methods." Avadel's position is apparently based on the word "system" in the claims' preamble, viewed in isolation. System need not be construed in a vacuum; it means just what it says. Avadel's attempt to exclude methods, however, lacks merit because it fails to account for both the entire preamble phrase and the claims as a whole.

The entire preamble phrase demonstrates that the REMS Patent's claims are directed to "treatment of a narcoleptic patient." And when the Court considers the claims as a whole, the claims demonstrate that "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." *Lyda v. CBS Corp.*, 838 F.3d 1331, 1339 (Fed. Cir. 2016). For example, claim 1 (and the additional steps set forth in the dependent claims) illustrates that the claims recite methods. The claimed methods are carried out—and misuse, abuse, and diversion of GHB are avoided—by requiring that, before the drug is dispensed, numerous pieces of information about both the patient and the prescriber are entered into and analyzed by the computerized system.

For instance and by way of example, the methods comprise:

- Identifying "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." *See* Ex. 10 at claim 1.
- Reconciling "inventory of the prescription drug before the shipments for a day or other time period are sent." *Id.*
- Identifying any "indicator of a potential misuse, abuse or diversion by the narcoleptic patient." *Id.*
- Identifying "an insurer to be contacted for payment for prescription drugs of an associated patient." *See id.* at claim 13.
- Using the computer database to identify "a current pattern or an anticipated pattern of abuse of the prescription drug." *See id.* at claim 14.
- Selecting "one or more controls for distribution … based on the identified pattern." *See id.* at claim 15.

Only if the answers to all inquiries are satisfactory will the methods allow the computer to be "used to notify the physician that is interrelated with the narcoleptic patient through the schema of the single computer database." *See id.* at claim 1.

Contrary to any argument that Avadel will likely make in its responsive brief, the claims of the REMS Patent do not improperly claim both a system and a method. Instead, and as "[b]oth common sense and a cursory inspection of relevant authorities demonstrate," a claimed method may be "limited to performance on a particular type of apparatus." *Collaboration Props., Inc. v.*

Tandberg ASA, No. 05-1940, 2006 WL 1752140, at *3 (N.D. Cal. June 23, 2006). Accordingly, the Federal Circuit has "made it clear" that the prohibition on hybrid claiming "is not implicated where a method claim 'recite[s] the physical structures of a system in which the claimed method is practiced.'" *Steuben Foods, Inc. v. Oystar USA, Inc.*, 520 F. Supp. 3d 310, 328 (W.D.N.Y. 2021) (quoting *Microprocessor Enhancement Corp. v. Texas Instruments, Inc.*, 520 F.3d 1367, 1374 (Fed. Cir. 2008)). That is the situation here.

Avadel's attempt to redefine the claims as systems as opposed to methods has no support in the intrinsic record and is based on an isolated reading of "system" in the claims. The Court should, thus, reject Avadel's proposal to construe "system" in the abstract because it ignores the context of the remainder of the preamble and the body of the claims.

b) Avadel's Answering Position

The parties' dispute over whether the '963 patent claims are directed to systems or methods is straightforward. The claims do not recite any method steps. Rather, they are directed to systems and recite the desired functions of the configuration of the claimed systems, consistent with the well understood meaning of "system" and the well understood format for system claims. Moreover, Jazz obtained other patents in the same family that are properly directed to methods, which bear the hallmarks of method claims. The '963 patent never should have been listed in the Orange Book, and Jazz's argument that the claims are directed to methods should be rejected.

(1) The Plain Language Establishes that the Claims Cover Systems

We begin with the claim language itself. Each of the three independent claims at issue contains the word "system," and recites various components of that system. *See* '963 patent at claims 1, 23, and 24 (comprising different system components). For example, claim 1 recites:

> A *computer-implemented system* for the 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* . . . .
>
> a *data processor* configured to . . . process a database query . . .

As another Court in this District has recognized, the "ordinary definition" of the commonly understood word "system" is "an integrated assemblage of hardware and/or software elements operating together to accomplish a prescribed end purpose." *See ABB Automation Inc. v. Schlumberger Resource Management Services, Inc.*, 2003 WL 1700013, at *4 (D. Del., Mar. 27, 2003); *see also* WILEY ELECTRICAL AND ELECTRONICS DICTIONARY (1st ed. 2004) at 766 ("A set of interrelated and/or interdependent components which form a complex whole serving for one or more purposes or functions.") (attached as Ex. G). In contrast, as the Federal Circuit has explained, the hallmark of a method claim is the recitation of "a series of acts or steps." *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002).

Consistent with their recitation of "systems" and not "methods," the '963 patent claims do not include *any* method steps. Rather, they recite the different components of the system—*e.g.*, a "data processor," "one or more computer memories," and a "computer database"—and the end purposes those components are "configured to" to accomplish. *See* '963 patent, claims 1, 23, 24. This is fully consistent with the plain meaning of a "system," as an assemblage of hardware and software elements or a set of interrelated components, not a method.

"Because the patentee is required to 'define precisely what his invention is' . . . it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.'" *Phillips*, 415 F.3d at 1312 (citation omitted). Disregarding the plain meaning of the claims as Jazz proposes and construing them as "methods" as opposed to "systems" would

turn that notice function on its head.[15] *See Phillips*, 415 F.3d at 1312 (citation omitted).

Jazz's proposal that the claims be construed as methods is predicated on a misguided analysis of the claim language. Indeed, Jazz's opening brief (a) misquotes the claim language by omitting the claims' recitation of the *components* of the computer-implemented system, such as "prescriber fields," and "data processor," and (b) replaces phrases describing the end purposes of the various system components (*e.g.*, "to identify," "to . . . reconcile"), with active verb language that purports to track method steps. Thus, as shown in the table below, Jazz changes claim language reciting "*prescriber fields for . . . storing information* sufficient to identify a physician or other prescriber of the company's prescription drug and information" to an ostensible method step of "*identifying* 'a physician or other prescriber of the company's prescription drug and information . . . .'" *Supra* at 48 (citing claim 1). Jazz also changes language reciting "a *data processor configured to* . . . reconcile inventory of the prescription drug" to an ostensible method step of "*reconciling* 'inventory of the prescription drug . . . .'" *Supra* at 48 (citing claim 1). And Jazz changes "a data processor configured to . . . identify[] . . . an indicator of a potential misuse, abuse, or diversion by the narcoleptic patient" to an ostensible method step of "*identifying* any 'indicator of a potential misuse, abuse, or diversion by the narcoleptic patient.'" *Supra* at 48 (citing

[15] Bedrock law establishes that there is a "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." *In re Kollar*, 286 F.3d at 1332. That distinction is not academic, for a device "capable" of performing the functions recited in a system claim can infringe, while infringement of a method claim requires actual performance of each method step. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 (Fed. Cir. 2008). Thus, "[u]nder section 271(a), the concept of 'use' of a patented method or process is fundamentally different from the use of a patented system or device." *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317 (Fed. Cir. 2005) (internal citations omitted). The distinction between such classes of patent subject matter is thus a fundamental part of the public notice function of a patent claim. *Phillips*, 415 F.3d at 1312.

claim 14).

Jazz's Asserted Requirement (quotations from Jazz's brief)	Actual Claim Limitation
"***Identifying*** '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.'"	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;
"***Reconciling*** 'inventory of the prescription drug before the shipments for a day or other time period are sent.'"	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;

"[P]atentees are charged with writing patents carefully and it is not within the province of the court to rewrite claims." *Evonik Degussa GmbH v. Materia Inc.*, No. 09-CV-636 (NLH/JS), 2013 WL 5780414, at *16 (D. Del. Sept. 30, 2013). Jazz's improper attempt to rewrite the claims through briefing only underscores the fact that the claims recite components of a computer system along with their intended end purposes, not method steps to be performed. *See Bio-Rad Labs, Inc. v. Int'l Trade Comm'n*, 998 F.3d 1320, 1331 (Fed. Cir. 2021) (rejecting patentee's argument because "it is premised on rewriting the claims" and patentee's "summary of the claim is not remotely close to what the claim says").

(2) The Remaining Intrinsic Evidence Further Supports Avadel's Proposed Construction

The remaining intrinsic evidence further demonstrates that the '963 patent claims are directed to systems, not methods. The specification discloses both a computer system and methods

of using that system, and distinguishes between the two. Figure 1 provides "a block diagram of a *computer system* for use in implementing the system and method of the present invention." *See* '963 patent at 2:29-31; Fig. 1. Consistent with the ordinary meaning of "system," Figure 1 describes the "system" as comprising hardware and/or software elements—a central processing unit, memory, storage, etc. This is precisely what the '963 patent claims.

By way of contrast, Figures 2A-C provide flowcharts describing a series of method steps that can be performed, in part, using the system in Figure 1. *See id.* at Figs. 2A-C; 2:32-34 ("FIGS. 2A, 2B and 2C are a flowchart describing a method for sensitive drug distribution at least partially utilizing a computer system such as that shown in FIG. 1"). This is what Jazz claimed in other, related patents not at issue here: methods of drug distribution using, in part, a computer system.

In fact, those related patent claims further underscore the propriety of adopting the ordinary meaning of "system." The '963 patent arises from Appl. No. 10/322,348, filed on Dec. 17, 2002. Other patents in the same family are unmistakably directed to the method embodiments and bear all the classic hallmarks of method claims: expressly reciting "methods"; using verbs to describe specific actions; and identifying steps to be performed. *See, e.g.*, U.S. Patent No. 7,765,106 at claim 1 ("A *therapeutic method* for treating a patient . . . comprising . . . receiving, only into an exclusive central computer system, all prescriptions.") (attached as Ex. H); U.S. Patent No. 8,457,988 at claim 1 ("A *method of treatment* of a narcoleptic patient . . . comprising . . . receiving in a computer processor all prescription requests") (attached as Ex. I).[16] The existence of those claims corresponds to the established distinction between claims directed to a "system" and those reciting a "method" as well as the plain and distinct meaning of those terms. Their existence

[16] Those patents have been invalidated, leaving only the system claims asserted here. D.I. 21 at 3.

further calls into question how Jazz can assert that the claims at issue here are directed to methods when related claims in the same family specifically used both the word "method" and, as required for such claims, described a series of steps to be performed. When Jazz wanted to claim methods, it knew how to do so, including by expressly reciting "methods" and the actions to be performed.

None of those hallmarks of method claims are present in the '963 patent claims. Jazz chose to prosecute system claims and admitted as much during proceedings before the Patent Trial and Appeal Board. *See Amneal Pharm. LLC v. Jazz Pharm., Inc.*, IPR2015-01903, Paper 14, Patent Owner Response at 2 (Jun. 3, 2016) (characterizing the challenged claims as being directed to "computer-implemented *systems*") (attached as Ex. J). Having previously taken the position that the claims of the '963 patent were system claims, it cannot now contend they should be treated as method claims.

(3) Functional limitations do not transform a system into a method

Jazz argues that the claims should nevertheless be construed as methods because they contain functional language. But functional language is routinely used to describe a system's components, and courts have repeatedly rejected Jazz's argument. For example, in *MasterMine Software, Inc. v. Microsoft Corp.*, the Federal Circuit held that the district court erred in concluding that a claim containing functional language recited both systems and methods. 874 F.3d 1307, 1313 (Fed. Cir. 2017).[17] The claims recited a "system" containing components capable of performing certain functions, such as a "reporting *module*" that "*presents* a set of user-selectable

[17] A claim that includes both system and method requirements is invalid for failing to "apprise a person of ordinary skill in the art of its scope." *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005). Jazz contends that "the claims of the REMS Patent do not improperly claim both a system and a method." *Supra* at 48. But there is no need to reach that invalidity issue because these claims are properly construed as systems without any method steps.

database fields . . . , *receives* from the user a selection . . . , and *generates* a database query . . . ." *Id.* at 1315. The Federal Circuit rejected the argument that functional descriptors of the system components converted the claims into methods: "Though claim 8 includes active verbs—presents, receives, and generates—*these verbs represent permissible functional language used to describe capabilities of the 'reporting module.'* Like the claims in [other Federal Circuit cases], the claims at issue here merely claim that the system possesses the recited structure which is capable of performing the recited functions." *Id.* at 1315-16 (internal citations and quotations omitted).

As in *MasterMine*, the claim terms highlighted by Jazz—*e.g.*, "reconcile," "to identify," "are selected"—describe the capabilities of the system components and do not convert the claims into methods. *See MasterMine*, 874 F.3d at 1313-16 (collecting cases); *Yodlee, Inc. v. CashEdge, Inc.*, No. C 05-01550 SI, 2006 WL 3456610, at *5 (N.D. Cal. Nov. 29, 2006) ("A simple analogy would be a claim which physically describes a pair of scissors designed to cut paper, then states, 'upon opening and closing the sharp edges of the scissors on a piece of paper, the paper is cut.' The language describes the capability of the scissors; it is function language. Infringement occurs upon the manufacturing and sale of scissors that are capable of cutting paper.").

Similarly, in *HTC Corp. v. IPCom GmbH & Co., KG*, the Federal Circuit held that the asserted claims were not method claims despite claim language reciting, among other things, "'a mobile station for use with a network including a first base station and a second base station that achieves a handover . . . by: *storing* link data for a link . . . *holding* in reserve the link resources" and four additional functions. 667 F.3d 1270, 1273 (Fed. Cir. 2012). As the Federal Circuit explained, the claims "do not recite a mobile station and then have the mobile station perform the six enumerated functions. The claims merely establish those functions as the underlying network environment in which the mobile station operates." *Id.* at 1277. Jazz's insistence that it can treat

the claims of the '963 patent as method claims because they include verbs is contrary to established Federal Circuit law and should be rejected.

(4) Jazz's Remaining Arguments Are Unavailing

Jazz's citation to the preamble language is likewise flawed. Jazz asserts that "[t]he *entire preamble phrase* demonstrates that the '963 patent's claims are directed to 'treatment of a narcoleptic patient,'" but omits the first portion of the preamble, which recites "[a] computer-implemented *system*." Moreover, the recitation of a purpose in the preamble is unremarkable—a preamble often sets forth the intended purpose of a system, composition, or apparatus. *See, e.g.*, *Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1310 (Fed. Cir. 2012) (claim required a "valve prosthesis for implantation in a body channel . . . ."); *see also, e.g.*, U.S. Patent No. 8,771,735, assigned to Jazz (Claim 1: "A compressed tablet of sodium oxybate *for oral delivery* of 0.5-1.25 g of sodium oxybate . . . .") (attached as Ex. K). Courts have rejected similar attempts to rely on preamble fragments reciting a therapeutic use for a system or device to transform the claims into method claims. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Microspherix LLC*, 814 F. App'x 575, 577 (Fed. Cir. 2020) (characterizing claims to a brachytherapy device *for use in radiation treatment* as "devices for treating cancers"); *Purdue Pharm. Prods. L.P. v. Actavis Elizabeth, LLC*, No. 12-5311 (JLL), 2014 WL 2624787, at *7-8 (D.N.J. June 11, 2014) (treating claims to "[a] solid unit dosage composition *for the treatment of MOTN insomnia*" as "composition" claims); *Pacific Biosciences Labs, Inc. v. Nutra Luxe MD, LLC*, No. 2012 WL 12845607, at *3, *10 (W.D. Wash. Mar. 21, 2012) (describing claim to "[a]n apparatus *for treatment of acne*" as an "apparatus" claim). The fact that the preamble explains that the system is one that pertains to a drug used for narcolepsy treatment does not convert the claims into a method claim.

Jazz relies heavily on *Lyda v. CBS Corp.*, but that case does not support a contrary result.

In *Lyda*, unlike here, the claims were directed to a system of method steps: "A system . . . comprising . . . *providing* . . . *having* . . *transmitting* . . . *collecting*, *correlating*, and *processing* . . . [and] *routing*." 838 F.3d 1331, 1335 (Fed. Cir. 2016) (quoting claim 7). The Federal Circuit held that because the asserted "system" claims "recite the same method steps as [method] claim 1 . . . the system claims should be treated as method claims." *Id.* Here, the claims of the '963 patent recite a list of computer components, not method steps, and *Lyda* is therefore irrelevant. Further, the complaint in *Lyda* alleged that the claims at issue were methods. In view of that allegation in the complaint, and at the pleading stage, the Federal Circuit agreed to "treat them as method claims for this 12(b)(6) analysis." *Id.* at 1340 n.3. In other words, the Court declined to engage in claim construction at the pleading stage. But we are now at the claim construction stage, not a pleading motion, and the claims at issue expressly require a system of things—a system *of computer memories and data processors*—not method steps.

c) Jazz's Reply Position

Avadel argues that "the '963 patent claims do not include *any* method steps." *Supra* at 50. As an initial matter, Avadel ignores that the "[c]laim construction analysis must begin and remain centered on the claim language itself." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Here, the claims recite a "computer-implemented ***system for treatment of a narcoleptic patient*** with a prescription drug that has a potential for misuse, abuse or diversion." Avadel tries to rewrite the claims and change "system" to "computer system," but that is not what the claims say, nor is it consistent with the different use of the different words "system" and "computer system" in the '963 Patent's specification.

The title of the '963 Patent is "Sensitive Drug Distribution System and Method." The word "system" in the claims must be read in conjunction with "drug distribution."[18] Indeed, the specification explains that the inventions were discovered because of "a need for a distribution system and method that directly addresses" several "abuses" that lead doctors and patients to misuse and divert sensitive drugs like GHB. Ex. 10, '963 Patent at 1:20-44. Avadel ignores that "system" is commonly used in the English language to mean a "formulated, regular, or special method or plan of procedure." *See* Ex. 12; *see also* Ex. 13 ("An organized and coordinated method; a procedure."); Ex. 14 ("[A] set of principles or procedures according to which something is done; an organized scheme or method"); Ex. 15 ("[A] method of organizing or doing things."). That is what the '963 Patent claims, and Jazz's construction, as well as the actual claim language, is consistent with methods being carried out using a particular computer.

In fact, Avadel's arguments support Jazz's position. Avadel correctly states that "Figure 1 [of the '963 patent] provides 'a block diagram of a *computer system* for implementing the system and method of the present invention.'" *Supra* at 53 (emphasis original). Avadel continues that "Figure 1 describes the 'system' as comprising hardware and/or software elements." *Id.* This is where Avadel goes wrong; Avadel removes "computer" before "system" and ignores that the description of Figure 1 uses both "computer system" and "system," and furthermore uses them to mean different things. In particular, as the description of Figure 1 states, the "computer system" "***implement[s]*** the system and method of the present invention." Ex. 10, '963 Patent at 2:29-31; *see also id.* at 3:56-58 ("FIG. 1 is a simplified block diagram of a computer system . . . for implementing at least a portion of the methods described herein.").

[18] This is consistent with other drug distribution systems cited in the '963 Patent—e.g., "***System*** for Thalidomide Education and Prescribing Safety (S.T.E.P.S.)." Ex. 10, '963 Patent at page 3.

Thus, the system and method are carried out using the "computer system" described in the specification. This is consistent with the inventors' use of "computer system" throughout the specification when they wanted to refer to the computer systems described therein, as opposed to the drug distribution system and method of the invention. *See id.* at 2:29-46, 3:20-23, 3:56-4:16.

Avadel's proposal would transform the claim language from a "***computer-implemented system*** for treatment of a narcoleptic patient" into a "***computer-implemented computer system*** for treatment of a narcoleptic patient." That transformation does not make sense within the context of the "Drug Distribution System and Method" described in the '963 Patent, nor the specific claim language directed to a "system for treatment of a narcoleptic patient."

Avadel argues that the Court should ignore the "treatment of a narcoleptic patient" language, because "[c]ourts have rejected similar attempts to rely on preamble fragments reciting a therapeutic use for a system or device to transform the claims into method claims." *Supra* at 56. But none of the cases dealt with drug distribution systems and, also, none "rejected" any such "attempts." In *Purdue Pharm. v. Actavis*, the court found the opposite: "that the claimed composition is 'for the treatment of MOTN insomnia' breathes life and meaning into [the claim]." No. 12-5311, 2014 WL 2624787, at *8 (D.N.J. June 11, 2014). In *Pacific Biosci. v. Nutra Luxe*, the court also expressly construed the preamble phrase "for treatment of acne" to have independent meaning. No. 10-0230, 2012 WL 12845607, at *5-7 (W.D. Wash. Mar. 21, 2012). Finally, *Merck Sharp v. Microspherix LLC* is not a *Markman* opinion and, therefore, the Court did not "reject" any proposed construction. 814 F. App'x 575 (Fed. Cir. 2020). Avadel cannot gloss over the fact that the claims here are directed to a "computer-implemented ***system for treatment of a narcoleptic patient***."

Furthermore, as previously explained, the body of the claims sets forth the method steps required to be performed by the claims. *See supra* at 48. Avadel accuses Jazz of "misquot[ing] the claim language by omitting the claims' recitation of the *components* of the computer-implemented system," and "replac[ing] phrases describing the end purposes of the various system components . . . with active verb language that purports to track method steps." *Supra* at 51. Jazz has not misquoted anything. And the Court need not search for "active verb language" to determine that the claims cover methods. Instead, the claims' use of the passive voice makes clear that they cover methods performed using a particular computer.

The asserted claims (as written) necessarily require an actor to perform the claimed methods using the defined computer. By way of example, the final clause of claim 1—using the passive voice—indicates that the computer is "***being used to notify*** the physician . . . ." Claim 3 likewise uses the passive voice and requires that "the prescription drug ***is shipped***." Along similar lines, claim 28 is a method where "filling of prescriptions ***is authorized*** for the company's prescription drug only if there is no record of incidents that indicate abuse . . . ."

"The passive voice focuses on an event that occurs without respect to a specific actor." *Dean v. United States*, 556 U.S. 568, 572 (2009). "To correctly ascertain the meaning of a sentence written in the passive voice, the sentence should be converted to the active voice." *Sci. Drilling Int'l, Inc. v. Pathfinder Energy Servs., Inc.*, No. 06-1634, 2006 WL 2882863, at *3 (S.D. Tex. Oct. 4, 2006). Here, when the passive voice is converted to the active, it becomes clear that some actor must carry out the method by using the specified computer: *to notify the physician*; *to ship the prescription; to authorize the filling of prescriptions*. These are clearly methods.[19]

[19] Avadel previously argued that the claims of the '963 Patent were indefinite, but has now specifically waived that argument (*see supra* at 54 n.18); thus, Jazz does not address it.

Avadel argues that "treat[ing] the claims of the '963 patent as method claims because they include verbs is contrary to established Federal Circuit law and should be rejected." *Supra* at 55-56. But in all of the cases Avadel relies on, the claims at issue did not set forth method steps in the passive voice. Instead, in each, the claims only used active language to describe system functionality. *See Yodlee, Inc. v. CashEdge, Inc.*, No. 05-1550, 2006 WL 3456610, at *4 (N.D. Cal. Nov. 29, 2006) ("The claims simply use active language to describe the *capability* of the apparatuses."); *HTC Corp. v. IPCom GmbH & Co.*, 667 F.3d 1270, 1277 (Fed. Cir. 2012) ("The claims merely establish those functions as the underlying network environment in which the mobile station operates."); *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1316 (Fed. Cir. 2017) ("[T]he claims here do not claim activities performed by the user.").

Avadel also wrongly contends that the claims should not be construed as methods because Jazz used the term "method" in the preamble of other patents. *See supra* at 53-54. As explained above, the '963 Patent also claims methods. Moreover, Avadel overlooks that the other method claims in the '963 Patent family have similar method steps as the '963 Patent:

Exemplary '963 Patent Method Step	**Similar Limitation in '963 Patent Family**
Claim 1 – "identifying that the narcoleptic patient is a cash payer . . . and being used to notify the physician"	'059 Patent (Ex. 16 at claim 8) – "[F]lagging that the patient paid cash for the prescription drug"
Claim 3 – "[T]he prescription drug is shipped to the narcoleptic patient if no potential misuse, abuse or diversion is found"	'059 Patent (at claim 1) – "[M]ailing or sending by courier the prescription drug to the patient only if no potential abuse is found by the patient to whom the prescription drug is prescribed"
Claim 24 / 28 – "[T]he filling of the prescriptions is authorized for the company's prescription drug only if there is no record of incidents that indicate abuse, misuse, or diversion"	'106 Patent (Ex. 17 at claim 1) – "[A]uthorizing the filling . . . of a prescription for the prescription drug that has been subjected to said multiple controls and has been approved for shipment to the patient"

The Federal Circuit permits inventors to "use different terms to define the exact same subject matter. Indeed [the Federal Circuit] has acknowledged that two claims with different terminology can define the exact same subject matter." *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006). As evidenced by the other method claims in the same family, under Avadel's proposal for "system," "the purported system claims asserted in this case are, in fact, method claims because the body of the claims require the performance of particular method steps." *Lyda v. CBS Corp.*, 838 F.3d 1331, 1339 (Fed. Cir. 2016).[20]

d) Avadel's Sur-Reply Position

Resolution of this dispute should be simple. The claims are directed to systems comprising "computer memories," a "computer database," and a "data processor" configured to perform certain functions. Jazz goes to great lengths to evade the plain meaning of the claim language by asking the Court to find that when the patent discloses a "drug distribution system and method," "system" is redundant because its common meaning is actually a "method." *Supra* at 57-59. Jazz would also have the Court distinguish between a "computer system" (an apparatus), and a "computer-implemented system" (allegedly a method). *Supra* at 59-60. Finally, Jazz asks the Court to disregard the many cases holding that a system claim does not become a method claim merely by reciting the functionality of the system, ignore the claims' recitation of computer components, and adopt a novel theory of claim construction that converts passive-voice functional

[20] Avadel's argument that "Jazz chose to prosecute system claims and admitted as much during proceedings before the [PTAB]" (*supra* at 54) rests on an improperly cropped quote. Jazz actually described the claims as "computer-implemented ***systems for treating a narcoleptic patient*** with a prescription drug that has a potential for misuse, abuse, or diversion, while preventing that misuse, abuse, and diversion ***by means of various controls***." Avadel Ex. J at 2; *see also id.* (explaining that "FDA would not have approved Xyrem without a ***method*** of restricting access to the drug that could ensure that its benefits would outweigh the risks to patients and third parties"). In other words, Jazz has consistently described the claims as covering a method of safely using GHB that relies on the use of a specific computer.

limitations into method steps based on a lone Texas ***contract case***. *Supra* at 60.

The law does not require such contortions. This is a straightforward exercise in applying the plain meaning of the claim language. Jazz chose to obtain claims directed to systems of hardware and software configured to perform certain functions—a decision that indisputably provided notice to the public of the scope of the claims. It should be held to that decision.

"Computer-implemented system" does not refer to methods: Jazz contends that the claimed "computer-implemented system" is really "a computer-implemented method." *Supra* at 58. But Jazz does not dispute Avadel's cases holding that the ordinary meaning of "system" is an "assemblage of hardware and/or software elements," and the specification provides no suggestion that the patent deviates from this ordinary meaning. Instead, Jazz argues that the specification distinguishes between a "computer system" (concededly a system) and a "system" (ostensibly a method that can be performed using a computer). *Supra* at 58.

First, that argument finds support in neither the patent nor logic. The patent distinguishes between system and method in its very title, being directed to both. And by its wording, a computer-implemented *system* falls within the genus of systems. It is a species of system that is computer-implemented. Indeed, the patent uses "system" and "computer system" interchangeably, including by referring to "Figure 1" using *both* terms. *Compare* '963 patent at 7:40-44 ("The central database . . . is a relational database running on the ***system of FIG. 1***, or ***a server based system*** having a similar architecture . . . .") *with id.* at 2:29-31 (Figure 1 "is a block diagram of ***a computer system*** for use in implementing the system and method of the present invention.").

Second, Jazz's litigation position stands in direct contrast to Jazz's decision to prosecute both system and method claims in this patent family. Indeed, Jazz has even pursued claims to "[a] computer-implemented ***system***" and "[a] computer-implemented ***method***" in the same application.

Ex. R at 22. Notably, Jazz did not disagree when the Examiner characterized "[s]ystem claim 2-5" as "repeat[ing] the subject matter of method claims 9-12 as a ***set of elements*** rather than a series of steps." Ex. S at 6; *see also* Ex. T at 14-18.

Third, Jazz previously admitted that "claim 1 of the '963 patent claims ***a specific machine*** that implements the misuse detection and prevention technologies underlying the inventions of [the REMS family of patents]." Ex. U, *Jazz Pharm., Inc. v. Watson Labs. Inc.*, C.A. No. 14-7757, D.I. 20 at 12 (D.N.J. Apr. 20, 2015). Indeed, Jazz further elaborated that "the '963 patent claims recite various possible ***hardware implementations*** of the central computer database." *Id.* at 14 (distinguishing the '106 patent (Ex. H), which is directed to methods). Jazz's concessions track the claim language and are at odds with its current position to avoid the plain meaning of that language.

A system can have a purpose without being a method: Jazz contends that the preamble language stating that the system is "for treatment of a narcoleptic patient" is limiting, *supra* at 59, but specifying the "treatment of a narcoleptic patient" as a field of use does not transform the system into a method. *See, e.g.*, *Hewlett-Packard Co. v. Bausch & Lomb Inc*., 909 F.2d 1464, 1466, 1468 (Fed. Cir. 1990) (claim to a "plotter system ***for forming images on a web*** comprising [means]" was an apparatus claim); *Synchronoss Techs., Inc. v. Dropbox, Inc.*, 987 F.3d 1358, 1361, 1369 (Fed. Cir. 2021) (claim to a "system ***for synchronizing data*** between a first system and a second system" was a system claim for infringement analysis).

There is no rule that the passive voice connotes method steps: Claim 1 requires that "the ***data processor is configured*** to process a second ***database query*** that ***identifies*** that the narcoleptic patient is a cash payer" and the identity of a relevant physician. '963 patent at claim 1. The claimed hardware and software is configured in that manner because "***said*** identifying" is

"an indicator of a potential misuse" and has the characteristic of "being used to notify the physician . . . ." *Id.* The "being" clauses thus explain that the database processor is to be configured to process the query and identify the relevant things because that information has value. It does not require further action. Numerous decisions confirm that system components may be described as taking action without becoming methods. For example, 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. *HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1277 (Fed. Cir. 2012); *see also, e.g.*, *Sensormatic Elecs., LLC v. Genetec (USA) Inc.*, C.A. No. 20-cv-760 (MN), 2021 WL 4453594, at *6 (D. Del. Sept. 29, 2021) (finding "claims are effectively reciting capability rather than required method steps" where a computer was required to "perform" certain actions).

Jazz nevertheless insists that claim 1 requires physician notification, advancing a novel theory of claim construction based on a contractual forfeiture case and the contract language "is terminated for cause." *Sci. Drilling Int'l, Inc. v. Pathfinder Energy Servs., Inc.*, C.A. No. H-06-1634, 2006 WL 2882863, at *3 (S.D. Tex. Oct. 4, 2006). According to Jazz, its use of the passive rather than active voice makes the claims (counterintuitively) more of a directive to be performed. *Supra* at 60. To the contrary, the use of the passive voice indicates capability of the element, not actual action. For example, in *3G Licensing, S.A. v. Blackberry Ltd.*, C.A. No. 17-82-LPS-CJB, 2018 WL 4375091 (D. Del. Sept. 13, 2018), the claim required a processor where "the processor is arranged to select one data record . . . the selection ***being performed*** on the basis of data identifying a . . . condition . . . , the identifying data ***being held*** in a further data record . . . ." *Id.* at *10. Contrary to Jazz's arguments, the court held that "the disputed claim language describes the functional features of the claimed data storage module and the operations of the claimed

processor" and "[n]othing in the claim requires a user to perform specific steps or take specific actions." *Id.*; *see also RightQuestion, LLC v. Samsung Elecs. Co.*, No. 2:21-CV-00238-JRG, 2022 WL 1154611, at *9 (E.D. Tex. Apr. 18, 2022) (holding that "the passive-voice language of the present claims . . . relate[s] to how a processor is configured").[21] The ordinary meaning of the claim language is clear.[22]

2. "Single/central computer database"

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
[single]/[central] computer database	No construction required	One and only one computer database, having the recited functionality

a) Jazz's Opening Position

The asserted claims recite both a "single computer database" and a "central computer database." These terms do not require construction. Claim construction is not an obligatory exercise in redundancy. *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). Rather, "[c]laim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." *Id.* Here, the disputed terms are ordinary words that mean just what they say. The parties do not dispute that the single/central computer database refers to a

[21] *See also Hewlett-Packard Co.*, 909 F.2d at 1466-67 (claim requiring "indentations repeatedly mating with the rough surface of the drive wheel as the web ***is driven*** back and forth . . . ." was an apparatus claim); *Edgewell Pers. Care Brands, LLC v. Albaad Massuot Yitzhak, Ltd.*, C.A. No. 15-cv-1188-RGA, 2017 WL 1900736, at *4-5 (D. Del. May 9, 2017) (claim to a tampon requiring a configuration "while said tampon assembly is ***being*** inserted into said body" had no method steps).

[22] Jazz argues that Avadel waived an argument that the claims are invalid as hybrid system/method claims. But Avadel has not forfeited any defenses that would arise from the Court adopting Jazz's proposed constructions. Avadel explained the argument fully in its invalidity contentions.

"single" or "central" computer database. There is no need to construe the terms further. *PureWick Corp. v. Sage Prod., LLC*, No. 19-1508, 2021 WL 619302, at *3 (D. Del. Feb. 17, 2021) ("I conclude that the meaning of the claim language at issue is clear and the terms are used in accordance with their ordinary meaning. No further construction is necessary.").

However, and despite that the parties do not dispute that the single/central computer database refers to a "single" (or "central") computer database, Avadel insists on adding the further limitation "[o]ne and only one computer database, having the recited functionality." In other words, Avadel seeks to replace "single" and "central" with "one and only one," and then to add these new words, which the applicants chose not to claim, to the words "computer database," which already appear in the claims in the disputed terms themselves. Avadel's proposed construction is an impermissible exercise in redundancy, and is contrary to the actual claim language and the intrinsic record.

The applicants chose to claim "single computer database" and "central computer database." They did not choose to replace "single" and "central" with "one and only one," as Avadel proposes, and there is nothing in the intrinsic record to support Avadel's proposal. In fact, claim 8, which depends from claim 1, further requires that the "single computer database is distributed among ***multiple computers***." Thus, to the extent that Avadel's proposed construction is somehow seeking to limit the number of computers that can comprise the "single computer database," Avadel's proposal runs afoul of the intrinsic record. Claim 8 could not logically depend from claim 1 were the Court to adopt Avadel's proposed construction. Indeed, "[b]y definition, an independent claim is broader than a claim that depends from it, so if a dependent claim reads on a particular embodiment of the claimed invention, the corresponding independent claim must cover that embodiment as well." *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir.

2022). Accordingly, the Court "must not interpret an independent claim in a way that is inconsistent with a claim which depends from it." *Id.* (citation omitted).

The specification further supports Jazz's reasoning and counters Avadel's proposal. Like the claims, the specification explains that, "in further embodiments, the central database may be distributed among multiple computers provided a query operates over all data relating to such prescriptions, prescribers and patients for the drug." *See* Ex. 10 at 8:2-5. In other words, the specification explicitly contemplates querying data for multiple "distributed" sources as part of the "central database." To the extent that Avadel's construction seeks to read this embodiment out of the claims, Avadel's proposal must be rejected. *See Chimie v. PPG Indus.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005) (excluding embodiments is "rarely if ever . . . correct").

The Court should reject Avadel's proposed construction. "[Single]/[central] computer database" requires no construction.

b) Avadel's Answering Position

The single/central computer database is an important part of the putative invention in the '963 patent claims. "The *exclusive central database* contains all data related to distribution of the drug, including patient, physician and prescription information. 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." '963 patent at 2:20-25. The claim language makes clear that one characteristic of that database is that it is a "single" database. "Single" means "one and only one." CONCISE OXFORD DICTIONARY OF CURRENT ENGLISH (9th ed. 1995) at 1295 ("one only, not double or multiple") (attached as Ex. L); RANDOM HOUSE WEBSTER'S DICTIONARY OF AMERICAN ENGLISH (1st ed. 1997) at 687 ("only one in number; one only") (attached as Ex. M). Jazz cites no evidence to the contrary, and the Court should adopt Avadel's proposed construction to prevent a dispute later.

The claim language: Asserted 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; . . . .

Asserted claims 25 and 28 depend from unasserted 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; . . . .

Claim 25 then adds a requirement that uses the term "the single computer database" with no antecedent basis other than "said central computer database," indicating that the claims use "central computer database" to mean "single computer database." *See* '963 patent at claim 25 ("The system of claim 24, wherein the one or more database queries are processed by the one or more data processors for identifying: 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* . . .").

The claims use the term according to its plain meaning—a *single* 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." For example, claim 8 requires that the "single computer database" be "distributed among multiple computers." Jazz argues that this means that the single computer database of claim 1 is not restricted to being hosted on only a single computer. That is true, and it supports Avadel's proposed construction. The applicants knew the difference between "single" and "multiple," and they chose to use the latter term to vary how the single database is *hosted*, not the number of databases being hosted. The database remains a single database. To treat "single computer

database" as permitting multiple computer databases flies in the face of the claim language.

The specification: The specification does not use the claim term "single computer database," but instead discusses "the central database" and similar variations. Like the claims, the specification shows that the applicants knew how to use words like "multiple" and never chose that language for the central database, which is always singular:

- Information is kept in "central database" and abuses are identified "by monitoring data in the database." '963 patent at 1:48-53.
- "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." *Id.* at 2:20-25.
- "The central database described above is a relational database running on the system of FIG. 1, or a server based system . . . . The database is likely stored in storage 140, and contains multiple fields of information as indicated at 700 in FIG. 7." *Id.* at 7:40-45; *see also id.* at Figs. 1, 7.
- "The central database ensures that all prescriptions, prescribers and patients are tracked and subject to such investigations. In further embodiments, the central database may be distributed among multiple computers provided a query operates over all data relating to such prescriptions, prescribers and patients for the drug." *Id.* at 7:67-8:5.

These disclosures do not support reading "single" out of "single computer database." Jazz's reliance on the disclosure that the "central database may be distributed among multiple computers" is unavailing. *Supra* at 68. As explained above, just because the central database may be hosted among multiple computers does not mean there can be multiple databases.

The prosecution history: The prosecution history is also consistent with Avadel's proposed construction. In the prosecution of a related application, the applicants made clear that a "single" computer database was the same thing as an "exclusive" or "sole" computer database. Appl. No. 10,322,348 ('348 Application) File History, 12/3/2007 Reply Brief Filed at 2 ("The term 'exclusive' means 'single' or 'sole,' and as pointed out above, Lilly et al. discloses that each entity typically maintains its own database. That is, there is not an *exclusive, single, or sole*

database disclosed in Lilly et al.") (footnote omitted) (attached as Ex. N). During prosecution of the same application, the applicants further explained that "[p]atients seeking prescriptions from different doctors will be detected, because the drug is tracked in *the central database*." '348 Application File History, 10/3/2005 Applicant Remarks at 17 (attached as Ex. O). They made the same point in a later response. *See* '348 Application File History, 3/29/2006 Applicant Remarks at 8-9 (explaining that a "central pharmacy" uses "the central database to keep track of all distribution of the sensitive drug." "This enables a much improved ability to monitor abuse situations. Patients seeking prescriptions from different doctors will be detected, because the drug is tracked in *the central database*. . . . [A]ll [entities that distribute the sensitive drug] must use *the same central database*.") (attached as Ex. P). Again, this is consistent with the applicants' choice of claim language, "single computer database," to mean one and only one computer database. Unless Jazz stipulates that "single" means "one and only one," the Court should so construe the term to avoid a dispute regarding its meaning down the road.

Avadel's proposal to include the clarifying phrase "having the recited functionality": The claim requires that the single computer database be capable of functioning in a particular way—in claim 1, it is a single computer database "having a database schema that contains and interrelates prescription fields, patient fields, and prescriber fields." '963 patent at claim 1. Each field then also has functionality. *See id.* Thus, by the claim term's plain meaning, it is the single (one and only one) database that must possess the required functionality.

c) Jazz's Reply Position

Avadel provides no basis to rewrite the terms "single computer database" and "central computer database" as "one and only one computer database." A database is simply a structured set of data held in a computer. Exs. 12-15. There is no support in the intrinsic record for Avadel's proposal to additionally read the phrase "one and only one" into the claims.

As the specification explains, the claimed "drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug. Information is kept in a central database regarding all physicians allowed to prescribe the sensitive drug, and all patients receiving the drug." Ex. 10, '963 Patent at 1:48-52. The method works—and abuse of GHB is identified and then prevented—"by monitoring data in the database for prescription patterns by physicians and prescriptions obtained by patients." *Id.* at 1:52-54. An "exclusive central database contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information." *Id.* at 2:20-22. The specification further explains that "the central database may be distributed among multiple computers provided a query operates over all data relating to such prescriptions, prescribers and patients for the drug." *Id.* at 8:2-5. The specification also states that "[i]t is recognized that many different organizations or schemas may be utilized" for the database. *Id.* at 7:47-48. Thus, the specification makes clear that data is maintained within an overarching single or exclusive central database.

The specification and file history do not require that "one and only one" database must be contained within the central database. Rather, the specification explains that the purpose of using a central database is to "ensure[] that all prescriptions, prescribers and patients are tracked and subject to [] investigations." *Id.* at 7:67-8:2. As Jazz explained during prosecution, the problem in the prior art was that multiple different entities "such as doctors, pharmacies, hospitals, pharmaceutical companies, insurance companies, government agencies, health care informatics companies, health researchers, managed care organizations, and other healthcare providers . . . typically maintain their own databases, and that such databases can be accessed by the other entities in the system as needed." Avadel Ex. N at 2. In other words, the disparate

databases of the prior art were not adequate to provide the necessary controls to prevent abuse, misuse, and diversion of a drug such as GHB. Jazz went on to explain that "[t]he term central database is used to encompass any real or virtual manifestation of a central database that facilitates evaluation of potential abuse patterns for distribution of the sensitive drug." Avadel Ex. O at 17. So, Jazz explained that the purpose of the central database was to facilitate the types of checks and controls to prevent abuse, misuse, and diversion of a drug such as GHB.

While Jazz stressed that the central database must be under central control, it did not limit it to "one and only one" database. The portions of the prosecution history Avadel relies on do not support its construction either. Jazz never asserted that the claimed methods must utilize "one and only one" database. To the contrary, Jazz distinguished prior art that failed to utilize an exclusive or centrally maintained database. As Jazz explained, the claimed method is most effective when information is stored in a central database, because "[p]atients seeking prescriptions from different doctors will be detected, because the drug is tracked in *the central database*." Avadel Ex. O at 17 (emphasis original). This is consistent with the specification. The use of a central database allows for more effective monitoring and prevention of prescription drug abuse. The prosecution history says nothing that would warrant limiting the single or central database to utilizing "one and only one" database.[23]

d) Avadel's Sur-Reply Position

Jazz ignores that the claim term is "***single*** computer database," and that Avadel showed that "single" means "one and only one." *Supra* at 68. As for claims 25 and 28, Jazz does not dispute that in these particular claims, "central computer database" means "single computer

[23] Similarly, there is no reason for adding Avadel's proposed language of "having the recited functionality." This language serves no purpose and lacks any support whatsoever.

database."

3. Reconciling inventory terms

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
reconcile inventory/reconciling inventory/cycle counted and reconciled	No construction required	Checking whether there is a mismatch between the aggregate amount of a drug reported in physical inventory and the aggregate amount in the database

a) Jazz's Opening Position

The claims require reconciling "inventory of the prescription drug before the shipments for a day or other time period are sent." There is no need to construe these plain, English words. *See U.S. Surgical Corp.*, 103 F.3d at 1568. Nonetheless, Avadel proposes that the reconciling inventory terms require an additional, unsupported limitation—a comparison of an ***aggregate*** physical inventory with an ***aggregate*** amount in the database. The word "aggregate" does not appear at all in the patent, nor is it otherwise supported by the record. The Court should, therefore, find that no construction is necessary.

b) Avadel's Answering Position

Jazz asserts that the claims require "reconciling 'inventory of the prescription drug before the shipments for a day or other time period are sent.'" *Supra* at 74. Claim 1 actually 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, claim 1. Either way, this term is not readily understandable—most people do not reconcile inventory as a part of their daily lives. And even people who *do* reconcile inventory would have a hard time understanding the claim because "to reconcile," in this context, means to bring multiple things into agreement, and claim 1 does not

explain what is being brought into agreement with what. *See* Ex. M at 616 ("4. to bring into agreement: *reconciled financial accounts*."). Other claims included the notion of inventory being "cycle counted," which is equally unclear.

Fortunately, the applicants explained what these phrases meant during prosecution. *See* '202 Application File History, 7/25/2013 Remarks at 9-13 (attached as Ex. Q). The applicants cited a portion of the specification calling for inventory to be "cycle counted and reconciled," and explained that "[a]s this example shows, *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." *Id.* at 11. Indeed, the applicants distinguished their claims over prior art (Mordai) that they said did not reconcile inventory: "Moradi 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.*

This explanation of the otherwise unclear language is highly relevant to what those terms mean. *See, e.g.*, *Univ. of Mass. v. L'Oreal S.A.*, -- F.4th--, 2022 WL 2111840, at *6, (Fed. Cir. June 13, 2022) ("the prosecution histories of the patents in question resolve the ambiguity surrounding the meaning of 'the adenosine concentration applied to the dermal cells' in the wherein clause"); *Osteoplastics, LLC v. ConforMIS, Inc.*, No. CV 20-405 (MN) (JLH), 2022 WL 610738, at *8 (D. Del. Feb. 14, 2022) ("[W]here the parties agree that there is no ordinary and customary meaning in the field of the invention, I would consider the provisional application's definition highly relevant to the question of what the inventor understood the term to mean."). Indeed, the language here constitutes lexicography. "Applicants can define (lexicography),

explain, or disavow claim scope during prosecution." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1343 (Fed. Cir. 2015).

In the face of this intrinsic evidence, Jazz's contention that there is no record support for requiring a comparison of "aggregate" amounts, (*supra* at 74), is inaccurate. Jazz does not dispute any other portion of Avadel's proposal and provides no explanation of its plain meaning. Avadel's proposed construction should be adopted.

c) Jazz's Reply Position

There is no need to construe these terms.[24] Yet Avadel seeks to limit them to inventory reconciliation that compares the "aggregate" amount in physical inventory to the "aggregate" amount in the database (*supra* at 75), as opposed to simply confirming that the inventory at a particular location matches what is expected based on the information in the database. Avadel's proposal ignores that dependent claim 20 requires the additional step of aggregate inventory reconciliation that Avadel seeks to read into independent claim 1. Claim 20 expressly requires that "current inventory is cycle counted and reconciled with database quantities before shipments for a day or other time period are sent." Thus, while independent claim 1, from which claim 20 depends, broadly includes within its scope aggregate inventory reconciliation, it does not require and is not limited to aggregate inventory reconciliation, because then claim 20 would be superfluous. *See Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed. Cir. 1999) ("[L]imitations stated in dependent claims are not to be read into the independent claim from which they depend."); *Beachcombers v. WildeWood Creative Products, Inc.*, 31 F.3d 1154, 1162 (Fed. Cir. 1994) (a construction that renders one claim superfluous to another is

[24] Avadel's attorney argument that "people who *do* reconcile inventory would have a hard time understanding the claim" (*supra* at 74-75) lacks any evidentiary support.

"presumptively unreasonable" and should be avoided).

Furthermore, the prosecution history does not support Avadel's construction. There was no clear and unmistakable disavowal. Instead, the applicants made clear that aggregate inventory reconciliation was but an "example" of the type of inventory reconciliation taught in the specification. *See* Avadel Ex. Q at 11; *see also id.* ("The '202 application includes ***examples*** in the specification of inventory reconciliation."). Asserting that the prior art does not disclose an exemplary embodiment of the claimed method does not limit the claims to that embodiment. *See, e.g.*, *Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 797 (Fed. Cir. 2019) (holding that statements that "describe how to make the claimed invention using the preferred [embodiment] in a 'new' way that is different from the prior art process [] are not statements clearly limiting [the scope of the invention to that preferred embodiment]"). The purpose of the statements in the prosecution was to distinguish prior art that taught determining "whether a pharmacy has a sufficient amount of the medication to fulfill a specific prescription order." *See* Avadel Ex. Q at 11. This was contrasted with the claimed method which compares the inventory in a particular location with the "database system inventory value to determine whether the physical inventory matches the database inventory value." *Id.* Thus, reconciling inventory only requires a comparison of what is in stock in a particular location to what is in the database. Avadel's attempt to import extra limitations into the claims should be rejected.

d) Avadel's Sur-Reply Position

Jazz finally explains what it thinks the term means: "confirming that the inventory at a particular location matches what is expected based on the information in the database." *Supra* at 76. Jazz thus agrees that "reconciling" requires checking for a mismatch between two values. As for "aggregate," Jazz's new claim differentiation argument contradicts Jazz's prior view that the patent never talked about aggregate inventory, and is in any event wrong. "Current" inventory is

the narrowed aspect of claim 20. And a mismatch can only be identified if aggregate amounts are used.

4. "Cash payer" terms

Term	Jazz's Proposed Construction	Avadel's Proposed Construction
database query that identifies that the narcoleptic patient is a cash payer/ "database queries . . . for identifying: that the narcoleptic patient is a cash payer . . ."	No construction required	Plain and ordinary meaning, which is the query identifies that the form of payment used by the patient was physical currency

a) Jazz's Opening Position

The claimed methods use the computer-implemented system to identify whether the narcoleptic patient is a cash payer. "Cash" is a well-understood term that requires no construction. *See, e.g.*, *Shire LLC v. Teva Pharm. USA Inc.*, No. 10-329, 2012 WL 975694, at *9 (D. Del. Mar. 22, 2012) (holding if the "term has a well understood meaning [it] does not require construction by the Court."). Despite this, Avadel's asks that the Court construe "cash" to mean that the "form of payment used by the patient was physical currency."

Nothing in the claims or intrinsic record limits "cash" to "physical currency"—whatever Avadel means by that. Nor does the extrinsic evidence at the time of invention support Avadel's apparently restrictive definition. Instead, Merriam-Webster's Collegiate Dictionary defined "cash" as "money or its equivalent (as a check) paid for goods or services at the time of purchase or delivery." *See* Ex. 11.

Accordingly, Avadel's proposed construction should be rejected, and the Court should find that no construction of this term is necessary.

b) Avadel's Answering Position

"A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning . . . ." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008) (construing well-understood phrase "only if"). The word "cash" is such a term. Ex. L at 202; Ex. M at 118. It can mean physical currency in the form of banknotes and coins as distinguished from checks and credit cards. When a small business posts a "Cash Only" sign, customers understand that they need to pay with bills and/or coins. Alternatively, it can mean money paid at the time of purchase in whatever form. If a buyer purchases a car from a dealership with "cash" rather than by financing the purchase, that likely means a check or electronic transfer of funds. Jazz argues for the latter understanding.

The '963 patent claims use "cash" in the former sense. They are directed to computer systems that help avoid the "misuse, abuse, or diversion" of sensitive drugs like GHB—useful for treating narcolepsy but also at risk of misuse. *See* '963 patent at claim 1; *id.* at 1:32-33. Those who use GHB to harm others must get it from somewhere, and one potential source is via prescriptions. As the '963 patent explains, a patient paying in cash might signal that the sale is not legitimate because the buyer is trying to conceal his true identity. '963 patent at 1:37-40. The implication is that these patients do not want to risk detection by using traceable forms of payment like a credit card. Avadel's proposed construction should be adopted.

c) Jazz's Reply Position

Avadel argues that the word "cash" has "more than one 'ordinary' meaning" and should, therefore, be construed. *See supra* at 79. But Avadel's argument provides no support for its limiting construction and, in fact, shows that "cash" has a much broader meaning than Avadel proposes (e.g., bills, coins, check, and/or electronic transfer of funds as opposed to just bills and

coins). Avadel does not claim that there is any lexicography or clear disavowal of that broader scope within the intrinsic record. "Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." *Home Diagnostics*, 381 F.3d at 1358. The "cash payer" terms are well understood, require no further construction, and Avadel's narrowing construction should be rejected.

d) Avadel's Sur-Reply Position

The claimed invention is intended to prevent abuse. The '963 patent does not indicate that it is suspicious when a patient makes a payment, just when an untraceable form of payment that is physical currency is used.

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