

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

AMENDED JOINT CLAIM CONSTRUCTION CHART

Pursuant to the Court’s Scheduling Orders (Civ. No. 21-691, D.I. 31, ¶ 11; D.I. 72), Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (together, “Jazz”), and Defendant Avadel CNS Pharmaceuticals, LLC (“Avadel”) (collectively, “the Parties”) hereby provide the following Amended Joint Claim Construction Chart for terms found in the asserted claims of U.S. Patent Nos. 8,731,963 (“the ’963 patent”), 10,758,488 (“the ’488 patent”),

10,813,885 (“the ’885 patent”), 10,959,956 (“the ’956 patent”), 10,966,931 (“the ’931 patent”), 11,077,079 (“the ’079 patent”), and 11,147,782 (“the ’782 patent”). The parties have agreed upon the construction of one claim term. The parties have identified six disputed terms, and the parties’ proposals and intrinsic evidence for the disputed claim terms are included in the chart.

The parties reserve the right to rely on intrinsic evidence identified by either party, and to amend and/or supplement the positions set forth in this Amended Joint Claim Construction Chart with additional intrinsic evidence and/or modified proposed constructions, in response to positions taken by the opposing party (including by any expert witnesses), and in response to any request or order by the Court. The parties also reserve the right to rely on additional intrinsic evidence, as well as extrinsic evidence, to the extent it is necessary to provide additional context or to rebut arguments made by the other party during claim construction briefing.

Agreed Upon Construction

Claim Term	Parties' Agreed Construction
<p>“by about 4 to about 6 hours”</p> <p>(’488 patent claims 1, 12; ’885 patent claim 1; ’956 patent claims 1, 11, 12, 25; ’931 patent claim 1)</p>	<p>Plain and ordinary meaning, which is at any point prior to approximately 4 hours or at any point prior to approximately 6 hours</p>

Disputed Constructions

No.	Claim Term	Jazz’s Proposed Construction	Jazz’s Intrinsic Evidence	Avadel’s Proposed Construction	Avadel’s Intrinsic Evidence
1	<p>“sustained release portion” (Jazz)</p> <p>“sustained release” (Avadel)</p> <p>(’488 patent claims 1, 4, 5, 11, 12; ’885 patent claims 1-4; ’956 patent claims 1, 4, 5, 10, 11, 12, 15, 16, 24, 25; ’931 patent claims 1-6)</p>	<p>Plain and ordinary meaning, i.e., the portion of the formulation that is not immediate release and that releases over a period of time</p>	<p>’488 Patent at 7:64-8:65; 14:5-8; 16:3-20¹</p> <p>’488 File History, 03-06-20 Response to Office Action at 8-9</p> <p>’488 File History, 03-05-20 Allphin Declaration at ¶ 10</p>	<p>A gradual, extended release, as opposed to releasing a majority of the drug within an hour upon exposure to intestinal pH</p>	<p>’488 patent at 3:1-6; 5:65-6:2; 8:7-14; Figs. 1-11; Exs. 1-13; Appl. No. 16/025,487, Mar. 6, 2020 Allphin Declaration at ¶¶ 3, 6-7, 10; Appl. No. 16/025,487, Mar. 6, 2020 Office Action Response at 8-9; Appl. No. 16/025,487, Mar. 6, 2020 Remarks at 6; Appl. No.</p>

¹ The ’488, ’885, ’956, and ’931 patents share a common specification.

No.	Claim Term	Jazz's Proposed Construction	Jazz's Intrinsic Evidence	Avadel's Proposed Construction	Avadel's Intrinsic Evidence
					13/071,369, May 28, 2013 Remarks at 16; Appl. No. 13/071,369, Sept. 16, 2014 Remarks at 14.
2	"controlled release component" ('079 patent claims 1, 10)	A formulation component with an active pharmaceutical ingredient having a release over a period of at least about 2 to about 8 hours	'079 Patent at 1:54-62; 2:48-56; 3:4-18, 6:4-11; 6:42-54; 6:55-7:8, 13:3-14:37	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	'079 patent at 1:63-67; 2:1-5; 2:10-12; 2:13-19; 2:20-24; 2:32-35; 4:32-34; 4:49; 5:41-47; 5:27-29; 5:61-6:4; 6:12-31; 6:32-34; 6:42-7:8; 7:9-12; 7:44-60; 8:22-24; 8:32-35; 9:6-8; 9:50-53; 10:1-2; 10:39-43; 11:61-64; 12:13-18; 12:44-46; 12:49-51; 12:52-59; 12:59-61; 12:62-64; 12:65-67; 13:3-4; 14:38-42; 15:3-6; 15:17-19; 15:53-58; 15:66-16:6; 16:26-29; 17:25-31; 17:58-65; 18:36-39; 19:4-9; 19:14-18; 19:53-55; 19:62-64; 20:13-15;

No.	Claim Term	Jazz's Proposed Construction	Jazz's Intrinsic Evidence	Avadel's Proposed Construction	Avadel's Intrinsic Evidence
					20:18-21; 20:62-66; 21:16-20; 21:25-30; Examples 1-7; Appl. No. 16/397,832, June 18, 2018 Allphin Declaration at 2; Appl. No. 16/397,832, Nov. 27, 2018 Applicant-initiated interview slides Inventor's Explanation of Technology; Appl. No. 16/397,832, Nov. 22, 2017 Response to Non-Final Office Action at 6.
3	"modified release particles" (782 patent claims 1, 14)	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	'782 patent at 1:56-66; 2:51-59; 5:50-61; 6:5-12; 6:43-55; 13:5-14:61 '782 File History, 06-18-21 Office Action at 5-6	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	'782 patent at 1:66-2:3; 2:4-8; 2:13-16; 2:17-22; 2:23-27; 4:32-35; 4:50-51; 5:42-49; 5:55-58; 5:62-6:5; 6:13-32; 6:21-24; 6:33-35; 6:42-7:9; 7:10-13; 7:45-57; 8:22-25; 8:34-36; 9:7-9; 9:53-55; 10:3-4; 10:41-

No.	Claim Term	Jazz’s Proposed Construction	Jazz’s Intrinsic Evidence	Avadel’s Proposed Construction	Avadel’s Intrinsic Evidence
					48; 11:64-12:1; 12:15-20; 12:46-48; 12:51-53; 12:54-61; 12:61-64; 12:64-67; 12:67-13:3; 13:5-6; 14:62-66; 15:27-30; 15:42-44; 16:11-16; 16:25-32; 16:52-55; 17:51-57; 18:17-24; 18:62-65; 19:30-35; 19:40-44; 20:12-14; 20:21-34; 20:39-43; 20:44-47; 21:21-25; 21:41-45; 21:50-55; Examples 1-7; Appl. No. 16/397,832, June 18, 2018 Allphin Declaration at 2; Appl. No. 16/397,832, Nov. 27, 2018 Applicant- initiated interview slides Inventor’s Explanation of Technology; Appl. No. 16/397,832, Nov. 22, 2017 Response to Non-

No.	Claim Term	Jazz's Proposed Construction	Jazz's Intrinsic Evidence	Avadel's Proposed Construction	Avadel's Intrinsic Evidence
					Final Office Action at 6.
4	<p>“whether the claimed ‘system’ includes methods of using the approved product”</p> <p>(’963 patent claims 1-23, 25, 28)</p>	<p>The ’963 patent claims methods of using a computer-implemented system to safely distribute gamma-hydroxybutyrate for treatment of a narcoleptic patient.</p>	<p>’963 Patent at 1:32-62, 3:24-43, claim 1, claim 2, claim 3, claim 13, claim 14</p>	<p>The claims are directed to systems and not to methods</p>	<p>’963 patent at Abstract; Figs. 1-13C; 1:41-44; 1:48-50; 2:29-31; 6:4-7; 7:40-43; claims 1-23, 25, 28.</p>
5	<p>“[single]/[central] computer database”</p> <p>(’963 patent claims 1, 4, 5, 7-9, 14, 21-23, 25)</p>	<p>No construction necessary</p>	<p>’963 Patent at 1:48-2:25, 7:40-54, 7:67-8:5</p>	<p>One and only one computer database, having the recited functionality</p>	<p>’963 patent at Figs. 1-13C, 13A-C; 1:48-52; 2:20-25; 4:38-53; 5:58-65; 6:4-7; 6:16-20; 6:30-37; 7:40-8:5; Figs 7, 13A-C; Appl. No. 10/322,348, Dec. 3, 2007 Reply Brief at 2; Appl. No. 10/322,348, Dec. 3, 2005 Response at 16-17; Appl. No. 10/322,348, Mar. 29, 2006 Response at 8-9.</p>

No.	Claim Term	Jazz's Proposed Construction	Jazz's Intrinsic Evidence	Avadel's Proposed Construction	Avadel's Intrinsic Evidence
6	<p>“reconcile inventory/reconciling inventory/cycle counted and reconciled”</p> <p>(’963 patent claims 1, 20, 23, 28)</p>	No construction necessary	’963 Patent at 6:4-7, 6:16-39	Checking whether there is a mismatch between the aggregate amount of a drug reported in physical inventory and the aggregate amount in the database	’963 patent at FIG. 6; 6:4-7; 6:16-39; Appl. No. 13/592,202, July 25, 2013 Response at 9-13.

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August 19, 2022

The Honorable Maryellen Noreika
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VIA ELECTRONIC FILING

Re: *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*
C.A. Nos. 21-691, 21-1138 & 21-1594 (MN)

Dear Judge Noreika:

Pursuant to the Court's August 1, 2022 Oral Order, counsel for the parties met and conferred via phone on August 11, 2022, in an attempt to reach agreement on constructions for the claim terms that remain in dispute. The meet and confer call lasted approximately 38 minutes and all of the disputed claim terms were discussed. The following counsel participated: F. Dominic Cerrito, Frank C. Calvosa, Gabriel P. Brier, and Jeremy Tigan for Jazz; Daralyn J. Durie, Herman H. Yue, and Daniel M. Silver for Avadel. The parties also corresponded by email after the call to further discuss potential compromises.

As a result of their efforts, the parties agreed on a proposed construction for "by about 4 to about 6 hours," as reflected in the attached Amended Joint Claim Construction Chart. Avadel also agreed to withdraw the "cash payer" claim terms from the list of disputed terms.

Respectfully,

/s/ Jeremy A. Tigan

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JAT/lo

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via CM/ECF and e-mail)