

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

**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 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 not agreed upon any constructions. The parties have identified eight disputed terms, and the parties’ proposals and intrinsic evidence for the disputed claim terms are included in the chart.

The parties dispute whether three additional terms for construction have been properly raised. (*See* D.I. 106, 107, 108.) The parties submit this Joint Claim Construction Chart with the understanding that it may need to be amended pending resolution of that dispute.

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 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.

Pursuant to Paragraph 11 of the Scheduling Order and this Court’s October 30, 2019 Standing Order Regarding Joint Claim Charts, copies of the patent and intrinsic evidence are not attached to the joint claim construction chart, and instead, will be included in a joint appendix with the joint claim construction brief.

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; 16:3-20<sup>1</sup></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. 13/071,369, May 28, 2013 Remarks at 16; Appl. No. 13/071,369, Sept. 16, 2014 Remarks at 14.</p>
2	<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, i.e., approximately 4 to approximately 6 hours</p>	<p>’488 Patent at 5:39-62</p>	<p>Plain and ordinary meaning, which is at any point prior to about 4 hours or at any point prior to about 6 hours</p>	<p>’488 patent at abstract, 3:66-67; 5:29; 6:10-14; Figs. 1-11; Exs. 1-13; Appl. No. 16/025,487, Mar. 6, 2020 Allphin Declaration at ¶¶ 9, 10, 13; Appl. No.</p>

<sup>1</sup> The ’488, ’885, ’956, and ’931 patents share a common specification.

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					16/025,487, July 2, 2018 Claims, claim 109, c; '487 application 3/6/20 Remarks at 10.
3	"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; 20:18-21; 20:62-66; 21:16-20; 21:25-30; Examples 1-7; Appl. No. 16/397,832, June 18, 2018 Allphin

No.	Claim Term	Jazz's Proposed Construction	Jazz's Intrinsic Evidence	Avadel's Proposed Construction	Avadel's Intrinsic Evidence
					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.
4	"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; 10:41-48; 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;

No.	Claim Term	Jazz's Proposed Construction	Jazz's Intrinsic Evidence	Avadel's Proposed Construction	Avadel's Intrinsic Evidence
					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-Final Office Action at 6.
5	"whether the claimed 'system' includes methods of using the approved product"  ( '963 patent claims 1-23, 25, 28)	The '963 patent claims methods of using a computer-implemented system to safely distribute gamma-hydroxybutyrate for treatment of a narcoleptic patient.	'963 Patent at 1:32-62, 3:24-43, claim 1, claim 2, claim 3, claim 13, claim 14	The claims are directed to systems and not to methods	'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.
6	"[single]/[central] computer database"  ( '963 patent claims 1,	No construction necessary	'963 Patent at 1:48-2:25, 7:40-54, 7:67-8:5	One and only one computer database, having the recited functionality	'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-

No.	Claim Term	Jazz's Proposed Construction	Jazz's Intrinsic Evidence	Avadel's Proposed Construction	Avadel's Intrinsic Evidence
	4, 5, 7-9, 14, 21-23, 25)				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.
7	“reconcile inventory/reconciling inventory/cycle counted and reconciled”  ('963 patent claims 1, 20, 23, 28)	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.
8	“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 necessary	'963 patent at 1:32-40, 6:40-50	Plain and ordinary meaning, which is the query identifies that the form of payment used by the patient was physical currency	'963 patent at Figs. 4A-B; 1:32-40; 6:44-50; Appl. No. 13/592,202, July 25, 2013 Response at 13-14.

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	('963 patent claims 1, 23, 25)				



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