

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (MN)
	)	
AVADEL PHARMACEUTICALS PLC,	)	
AVADEL US HOLDINGS, INC., AVADEL	)	
SPECIALTY PHARMACEUTICALS, LLC,	)	
AVADEL LEGACY PHARMACEUTICALS,	)	
LLC, AVADEL MANAGEMENT	)	
CORPORATION and AVADEL CNS	)	
PHARMACEUTICALS LLC,	)	
	)	
Defendants.	)	

**STIPULATED PROTECTIVE ORDER**

WHEREAS, discovery in the above-entitled action (“Action”) may involve the disclosure of certain documents, things and information in the possession, custody or control of Plaintiff Jazz Pharmaceuticals, Inc. (“Jazz Pharmaceuticals”), Defendants Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC (collectively “Avadel”), or non-parties that constitute or contain trade secrets or other confidential research, development or commercial information within the meaning of Rule 26(c) of the Federal Rules of Civil Procedure (“Fed. R. Civ. P.”) and as further set forth below;

WHEREAS, the parties, through counsel, stipulate to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information; and

WHEREAS, the parties, through counsel, stipulate that good cause exists for the entry of this Protective Order pursuant to Fed. R. Civ. P. 26(c) to protect against improper disclosure or use of confidential information produced or disclosed in this case.

IT IS HEREBY STIPULATED AND AGREED, SUBJECT TO THE APPROVAL AND ORDER OF THE COURT, as follows:

1. **Scope of Protective Order.** This Protective Order shall apply to all information, documents and things produced or within the scope of discovery in this Action, including, without limitation, all testimony adduced and documents and things marked as exhibits at depositions, hearings, and at trial, documents or things produced in response to requests for the production of documents and things, answers to interrogatories, responses to requests for admission and all other discovery taken pursuant to the Federal Rules of Civil Procedure, correspondence between counsel, as well as hearing or trial transcripts, matters in evidence, and any other information furnished, directly or indirectly, by or on behalf of any party to this Action or any THIRD PARTY to the extent such material is designated “CONFIDENTIAL INFORMATION” or “HIGHLY CONFIDENTIAL INFORMATION” in accordance with ¶¶ 2 and 4 of this Protective Order.

This Protective Order shall also govern any designated record of information produced in this action pursuant to required disclosures under any federal procedural rule or District of Delaware local rule, and any supplementary disclosures thereto.

2. **Definitions.** The terms “CONFIDENTIAL INFORMATION,” “HIGHLY CONFIDENTIAL INFORMATION” and “THIRD PARTY” or “THIRD PARTIES,” as used herein, shall mean the following:

- a. “CONFIDENTIAL INFORMATION” means any tangible thing or oral testimony that contains or reveals what a party or THIRD PARTY considers to be its trade secret, business confidential, or proprietary research, development, commercial, or financial information. It may include, without limitation, documents produced in this action, during formal discovery or otherwise; information of non-parties which

the producing or designating party is under an obligation to maintain in confidence; initial disclosures; answers to interrogatories and responses to requests for admission or other discovery requests; deposition or hearing transcripts; affidavits; exhibits; experts' reports; memoranda of law; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal or otherwise disclose such confidential information shall also be deemed "CONFIDENTIAL INFORMATION." Information originally designated as "CONFIDENTIAL INFORMATION" shall not retain that status after any ruling by the Court denying such status to it. Each party shall act in good faith in designating information as "CONFIDENTIAL INFORMATION."

- b. "HIGHLY CONFIDENTIAL INFORMATION" means all information regarding
- (i) confidential, highly sensitive, and/or proprietary information pertaining to marketing, sales, revenues, profits, forecasts, or business plans or strategies for any existing products or products in development;
  - (ii) past, current or future products other than sodium oxybate-containing drug products,
  - (iii) past, current or future plans regarding treatment indications for sodium oxybate-containing drug products other than the treatment indications for which FDA approval is or has been sought;
  - and (iv) scientific or technical information relating to, referring to, or concerning Xyrem®, Xywav™, FT218, Drug Master Files ("DMF") related in any way to Xyrem®, Xywav™ and/or FT218, and/or the associated products (including compositions, methods, uses, or processes) that constitute or reflect trade secrets or other proprietary information, including, but not limited to, draft patent

applications, invention disclosures, non-public patent filings; confidential research, development, testing and studies relating to drug products, methods, uses or processes; any correspondence or draft correspondence with the FDA regarding FT218; any research, development, testing, analysis and/or studies, including analytical data relating to any chemical materials used to produce a sodium oxybate-containing composition that the producing party reasonably believes the disclosure of which is likely to cause harm to the competitive position of the party producing the information of could be used in patent prosecution by the party receiving the information to the competitive disadvantage of the party producing the information. It may include, without limitation, documents produced in the actions, during formal discovery or otherwise; information of non-parties which the producing or designating party is under an obligation to maintain in confidence; initial disclosures; answers to interrogatories and responses to requests for admission or other discovery requests; deposition or hearing transcripts; affidavits; exhibits; experts' reports; memoranda of law; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all drafts, copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal or otherwise disclose such highly confidential information shall also be deemed "HIGHLY CONFIDENTIAL INFORMATION." Information originally designated as "HIGHLY CONFIDENTIAL INFORMATION" shall not retain that status after any ruling by the Court denying such status to it. Each party shall act in good faith in designating information as "HIGHLY CONFIDENTIAL INFORMATION."

c. “THIRD PARTY” or “THIRD PARTIES” means any person or entity who is not a named party in this Action.

3. **THIRD PARTIES under the Protective Order.** If a THIRD PARTY provides discovery to any party in connection with this Action, and if the THIRD PARTY so elects, then the provisions of this Protective Order shall apply to such discovery and the parties will treat all information that is produced by such THIRD PARTY in accordance with the terms of this Protective Order to the extent it is designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. Under such circumstances, the THIRD PARTY shall have the same rights and obligations under this Protective Order as held by the parties to this Action. Because third parties may be requested to produce documents containing information that a party considers CONFIDENTIAL or HIGHLY CONFIDENTIAL, at the request of any party all documents produced by a third party in this action shall be treated as if designated HIGHLY CONFIDENTIAL under this Protective Order for a period of seven (7) days after production in order to allow the parties time to review the documents and make any appropriate designations hereunder.

4. **Designation.** Each party shall have the right to designate information as CONFIDENTIAL or HIGHLY CONFIDENTIAL subject to this Protective Order. To the extent that material is designated CONFIDENTIAL or HIGHLY CONFIDENTIAL, such material shall only be revealed to or used by limited categories of individuals, as provided for in ¶¶ 13-14, and shall not be communicated in any manner, either directly or indirectly, to any person or entity except as provided herein. Any copies of such material, abstracts, summaries or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed CONFIDENTIAL or HIGHLY CONFIDENTIAL (consistent with the designation of the

originals), and the same terms regarding confidentiality of these materials shall apply as to the originals. The procedures for designating materials as CONFIDENTIAL or HIGHLY CONFIDENTIAL are as follows:

a. **Designation of Documents and Things.** The producing party shall label or mark each page of each document and thing that constitutes or contains CONFIDENTIAL INFORMATION with the legend “CONFIDENTIAL,” or otherwise mark or designate in writing the materials as CONFIDENTIAL INFORMATION and subject to the Protective Order when the document or thing is produced to the receiving party. The producing party shall label or mark each page of each document and thing that constitutes or contains HIGHLY CONFIDENTIAL INFORMATION with the legend “HIGHLY CONFIDENTIAL,” or otherwise mark or designate in writing the materials as HIGHLY CONFIDENTIAL INFORMATION and subject to the Protective Order when the document or thing is produced to the receiving party.

Anything that cannot be so marked shall be designated by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto. Each page of each document and each thing produced pursuant to discovery in this Action shall also bear a unique identifying number.

Documents and things produced without a legend designating the material as either CONFIDENTIAL or HIGHLY CONFIDENTIAL shall not be subject to this Protective Order unless otherwise agreed by the parties, ordered by the Court, or otherwise designated as either CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION in accordance with the provision of ¶ 9 of this Protective Order. Inspection of documents or things by any party shall be conducted by persons eligible

under ¶¶ 13-14 below. Such persons shall initially treat all information obtained during or from any inspection as containing HIGHLY CONFIDENTIAL INFORMATION until such time as copies of documents or things from the inspection are produced, and, thereafter, such produced documents and things shall be treated in accordance with any confidentiality designation appearing on the document or thing at the time of its production.

Documents and things produced or made available for inspection may be subject to redaction, in good faith by the producing party, of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION that is neither relevant to the subject of this litigation nor reasonably calculated to lead to the discovery of admissible evidence, or is subject to the attorney-client privilege, work-product immunity, or other applicable privilege or immunity from production recognized under the Federal Rules of Evidence. Each such redaction, regardless of size, shall be clearly labeled. This Paragraph shall not be construed as a waiver of any party's right to seek disclosure of redacted information. All documents redacted based on attorney-client privilege or work-product immunity shall be listed on a privilege log in accordance with Federal Rule of Civil Procedure 26(b)(5) and exchanged at a mutually agreeable date and time.

b. **Designation of Written Discovery.** Pleadings, Interrogatories, Requests for Admission, Written Testimony, and any other written discovery which in good faith are deemed by the disclosing party to contain or comprise CONFIDENTIAL INFORMATION will be so identified and marked "CONFIDENTIAL" by that party. Pleadings, Interrogatories, Requests for Admission, Written Testimony, and any other written discovery which in good faith are deemed by the disclosing party to contain or

comprise HIGHLY CONFIDENTIAL INFORMATION will be so identified and marked “HIGHLY CONFIDENTIAL” by that party.

c. **Designation of Deposition Transcripts.** Deposition transcripts containing either CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION may be designated as subject to this Protective Order either on the record during the deposition or by providing written notice within thirty (30) days following receipt of the official transcripts of the deposition.

All deposition transcripts not previously designated shall be deemed to be, and shall be treated as HIGHLY CONFIDENTIAL for a period of thirty (30) days after receipt of the official transcript of the deposition by the designating party, and the transcript shall not be disclosed during such time by a non-designating party to persons other than those persons qualified to receive such information pursuant to this Protective Order. After thirty (30) days after receipt by the designating party, if a transcript has not been designated, the aforementioned testimony shall no longer be treated as HIGHLY CONFIDENTIAL INFORMATION unless the parties otherwise agree.

The parties agree to mark at least the first page of all copies of deposition transcripts that contain testimony, or that append exhibits, designated as either CONFIDENTIAL or HIGHLY CONFIDENTIAL with the legend “CONFIDENTIAL INFORMATION” “HIGHLY CONFIDENTIAL INFORMATION,” commensurate with the designation. This paragraph does not limit any party’s right to challenge any presumptive designation or preclude a producing party from designating testimony or transcripts as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.



d. **Designation of Hearing Testimony or Argument.** With respect to testimony elicited during hearings and other proceedings, whenever counsel for any party deems that any question or line of questioning calls for the disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, counsel may ask the Court to designate on the record that the disclosure is subject to confidentiality restrictions. Whenever matter designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is to be discussed in a hearing or other proceeding, any party claiming such confidentiality may ask the Court to have excluded from the hearing or other proceeding any person who is not entitled under this Order to receive information so designated.

5. **Limitations on Attendance at Depositions.** Counsel for a producing party may request that all persons other than the witness, counsel for the witness (who signs the Undertaking attached as Exhibit A if a non-party witness), the court reporter, and those individuals specified in ¶¶ 13-14, as applicable, leave the deposition room during the portion of the deposition that inquires about or discloses subject matter that counsel for the producing party believes to be CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION hereunder. If individuals other than those specified in the previous sentence fail to leave the deposition room during any portion of the deposition that inquires about or discloses what counsel for the producing party believes to be CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, counsel for the producing party may seek relief from the appropriate Court and, pending resolution of its request for relief, instruct the witness not to answer questions relating to, or limit disclosure of, the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION at issue.

6. **Limitations on Attendance at Hearings or Trial.** Counsel shall confer with the Court regarding any requested procedures to protect the confidentiality of material marked, labeled, or otherwise designated as either CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION that a party or any of its witnesses may use, refer to, disclose, or admit into evidence during trial or any hearing in this Action. Counsel may request that attendance at a hearing or at a trial session in this Action at which material designated CONFIDENTIAL INFORMATION will be used or disclosed be limited for the time period during which either CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION will be used or disclosed to individuals entitled to have access to such materials under the terms of this Protective Order.

7. **Proper Use and Disclosure of Designated Information.** Subject to the limitations and restrictions of this Protective Order and any further order regarding confidentiality that the Court may enter, material marked, labeled or otherwise designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION as described in this Protective Order may be used solely to prepare for and conduct discovery, to prepare for trial and to support or oppose any motion in this Action, and may be used in testimony at trial, offered into evidence at trial and/or hearings on motions subject to such procedures mandated by the Court. Nothing herein shall be construed to affect in any way the admissibility of any document, testimony or other evidence at trial.

Material designated as either CONFIDENTIAL or HIGHLY CONFIDENTIAL, and all information derived therefrom, shall be used only by persons permitted access to such information under this Protective Order, shall not be disclosed by the receiving parties to any party or person not entitled under this Protective Order to have access to such material, and shall not be used by

the receiving parties for any purpose other than in connection with this action, including without limitation for any research, development, manufacture, patent prosecution, post-grant review, post-grant patent challenges (*e.g.*, inter partes review or supplemental examination), financial, commercial, marketing, regulatory, business, or other competitive purpose (except for settlement of the above-captioned case).

For the length of this litigation plus one year after a final, non-appealable judgment in this litigation, any person receiving information designated as HIGHLY CONFIDENTIAL INFORMATION under this Order may not engage, formally or informally, directly or indirectly, in any U.S. or foreign patent prosecution (as used herein, “patent prosecution” means drafting and/or amending patent claims, but is not intended to preclude involvement in reexaminations, oppositions, inter partes reviews, or similar post-grant proceedings before the U.S. Patent and Trademark Office or any foreign patent office as long as such individuals are not involved directly or indirectly in drafting or amending patent claims or providing recommendations regarding the drafting or amending of patent claims) for any patents or patent applications that, if issued: i) could be listed in the Orange Book for Xyrem®; ii) could cover once-nightly formulations of sodium oxybate or components thereof; iii) could cover methods of treatment using once-nightly formulations of sodium oxybate; iv) could cover any process, machine, manufacture, or composition of matter related to the distribution of sensitive drugs, including oxybate or v) could cover processes for manufacturing once-nightly formulations of sodium oxybate. The patent prosecution bar in this paragraph shall not apply to patent applications containing claims (either in the application as filed or as amended) that are limited to: (1) methods of treating diseases or conditions other than narcolepsy or any symptoms thereof with administration of sodium oxybate

or GHB or a salt thereof; or (2) non-once-nightly formulations containing sodium oxybate or GHB or a salt thereof that could not cover a once-nightly formulation or any components thereof.

For the length of this litigation plus one year after a final, non-appealable judgment in this litigation, any person receiving information designated as HIGHLY CONFIDENTIAL INFORMATION may not be involved, directly or indirectly, in drafting or amending any petition or other correspondence before or involving the FDA or equivalent foreign agency concerning any once-nightly sodium oxybate product. Notwithstanding the foregoing sentence, nothing in this paragraph prevents the person from performing work before the FDA or equivalent foreign agency solely for obtaining or maintaining approval of the Receiving Party's own new drug application provided that no HIGHLY CONFIDENTIAL INFORMATION of the Producing Party is used or disclosed.

Absent written consent of the producing parties or further order of this Court, all persons receiving information designated either CONFIDENTIAL or HIGHLY CONFIDENTIAL are expressly prohibited from using or disclosing such information in connection with any practice before or communication with (post-grant patent challenges, citizens petitions, and other filings) the United States Patent and Trademark Office, the FDA, the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction.

**8. Storage of CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION.** The recipient of any CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION shall maintain such information in a secure and safe manner and shall exercise the same standard of due and proper care with respect to the storage, custody, use and/or dissemination of such information as is exercised by the recipient with respect to his/her/its own proprietary information.

9. **Inadvertent Production of CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION.** If a party inadvertently produces or provides discovery of any CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION without labeling or marking it as provided in this Protective Order, the producing party may give written notice to the receiving party or parties, within ten (10) business days after becoming aware of the inadvertent production, that the document, thing or other discovery information, response or testimony is CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, as the case may be, and should be treated as such in accordance with the provisions of this Protective Order. The producing party will also provide copies of the properly marked information (*e.g.*, documents, discovery responses, transcripts, things, and/or all other information within the scope of this Protective Order). Upon receipt of such notice and properly marked information, the receiving party or parties shall return or destroy said unmarked or incorrectly marked information to the extent practicable and not retain copies thereof, and shall undertake best efforts to correct any disclosure of such information contrary to the redesignation. Prior to receipt of such notice, disclosure of such documents, things, information, responses and testimony to persons not authorized to receive CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, as the case may be, shall not be deemed a violation of this Protective Order.

10. **Limitations on Advice to Clients.** It is understood that counsel for a party may give advice and opinions to his or her client based on his or her evaluation of designated CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION received by the party, provided that such rendering of advice and opinions shall not reveal the

content of such information, except by prior written agreement with counsel for the producing party.

11. **Discovery of THIRD PARTY Information.** A producing party may redact the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION of a THIRD PARTY that is in its possession where the producing party is under an obligation not to disclose such information, provided that the producing party shall identify the THIRD PARTY to the receiving party and shall not impede discovery by the receiving party from said THIRD PARTY.

12. **Inadvertent Production of Privileged or Work Product Information.** When the inadvertent or mistaken disclosure of any information, document or thing protected by privilege or work-product protection is discovered by the producing party and brought to the attention of the receiving party, the receiving party's treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5)(B) and Federal Rule of Evidence 502(b). For purposes of any analysis under Federal Rule of Evidence 502(b), if the producing party certifies in good faith that the production was inadvertent and reasonable steps were taken to prevent disclosure, then it shall be treated as such.

When making a claim of privilege, the producing party shall include a privilege log entry reflecting the privileged material. Upon receipt of a claim of privilege, the receiving party shall destroy all copies of the privileged material. If the receiving party wishes to contest a claim of privilege, the receiving party shall notify the producing party within seven (7) days. Thereafter, the parties shall meet and confer promptly and, if the parties are unable to resolve the dispute, the parties shall contact the Court's Judicial Administrator to schedule an argument to resolve the dispute pursuant to the Court's Rule 16 Scheduling Order in this case. The receiving party shall

not retain a copy of the privileged material for the purposes of challenging the claim, and any challenge shall be based on the privilege log entry provided by the producing party.

13. **Access to CONFIDENTIAL INFORMATION.** Material marked, labeled or otherwise designated CONFIDENTIAL INFORMATION as described in this Protective Order shall be deemed and treated as CONFIDENTIAL INFORMATION hereunder, unless and until the Court rules to the contrary, and access thereto or disclosure thereof shall be limited, unless and until the Court rules that there may be further disclosure, to the following individuals:

a. Quinn Emanuel Urquhart & Sullivan, LLP and Morris, Nichols, Arsht & Tunnell LLP, litigation counsel of record for Plaintiff Jazz Pharmaceuticals, and their partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION.

b. Two (2) in-house counsel for Jazz Pharmaceuticals, to be designated at a later time, and clerical staff (including paralegals) working directly with them (who sign the Undertaking attached as Exhibit A), whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION. Jazz Pharmaceuticals represents that the designated in-house counsel, after receipt of CONFIDENTIAL INFORMATION, and in addition to the other terms of this Protective Order, shall not disclose to the FDA, the U.S. Patent and Trademark Office, or any nonparty, any CONFIDENTIAL INFORMATION. Notwithstanding the foregoing provisions, in-house counsel shall be permitted to advise Jazz Pharmaceuticals regarding legal strategy and the pending litigation; provided, however, that the CONFIDENTIAL INFORMATION is not thereby disclosed.

c. Latham & Watkins LLP, Durie Tangri LLP, and McCarter & English, LLP, litigation counsel of record for Defendant Avadel, and their partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION.

d. Two (2) in-house counsel for Avadel, to be designated at a later time, and clerical staff (including paralegals) working directly with them (who sign the Undertaking attached as Exhibit A), whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION. Avadel represents that the designated in-house counsel, after receipt of CONFIDENTIAL INFORMATION, and in addition to the other terms of this Protective Order, shall not disclose to the FDA, the U.S. Patent and Trademark Office, or any nonparty, any CONFIDENTIAL INFORMATION. Notwithstanding the foregoing provisions, in-house counsel shall be permitted to advise Avadel regarding legal strategy and the pending litigation; provided, however, that the CONFIDENTIAL INFORMATION is not thereby disclosed.

e. Outside consultants or experts and their staffs retained by the parties or their attorneys for purposes of this action, who are not objected to pursuant to ¶ 14, and who first agree to be bound by the terms of this Protective Order;

f. The Court before which this Action is pending and their authorized staff court reporters;

g. Court reporters, videographers, and their respective staffs employed in connection with this action;



h. Any interpreter and any typist or transcriber used by the interpreter, who first agrees to be bound by the terms of this Protective Order;

i. Any Third Party Vendors as defined below, who first agree to be bound by the terms of this Protective Order; and

j. Any other person as to whom the parties agree in writing.

14. **Access to HIGHLY CONFIDENTIAL INFORMATION.** Material marked, labeled or otherwise designated HIGHLY CONFIDENTIAL INFORMATION as described in this Protective Order shall be deemed and treated as HIGHLY CONFIDENTIAL INFORMATION hereunder, unless and until the Court rules to the contrary, and access thereto or disclosure thereof shall be limited, unless and until the Court rules that there may be further disclosure, to the persons identified in ¶ 13.a., ¶ 13.c. and ¶ 13.e-j. In addition, one individual eligible to receive CONFIDENTIAL INFORMATION pursuant to ¶ 13.b. and ¶ 13.d. shall be permitted access to HIGHLY CONFIDENTIAL INFORMATION; provided, however, that such individual shall be disclosed to the producing party's outside counsel before any HIGHLY CONFIDENTIAL INFORMATION is shared with such person. For the avoidance of doubt, nothing herein precludes the parties from agreeing in writing to allow additional persons eligible to receive CONFIDENTIAL INFORMATION pursuant to ¶ 13.b. and ¶ 13.d. access to a producing party's HIGHLY CONFIDENTIAL INFORMATION.

15. **Retention of Experts and Outside Consultants.** Disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL shall not be made to any such outside consultant described in ¶ 13.e. for a period of seven (7) days after serving the party providing discovery with a signed Undertaking in the form of the annexed Exhibit A, a list of all cases in which, during the

previous five (5) years, the expert or consultant has provided a written expert report or testified at trial or by deposition, and a current curriculum vitae of the outside consultant.

Counsel for the party providing discovery may, within the seven (7) day period, serve a notice of objection if a reasonable basis for such objection exists. If the notice is served, no CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION will be disclosed to such outside consultant. Within seven (7) days after service of the objection, if the parties are unable to reach any agreement over the disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION to the expert or consultant, the parties shall contact the Court's Judicial Administrator to schedule an argument to resolve the dispute pursuant to the Court's Rule 16 Scheduling Order in this case. Until the dispute is resolved, no CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall be disclosed to the outside expert or consultant until the Court rules or the parties agree that such disclosure may be made. Failure to contact the Court's Judicial Administrator to schedule an argument to resolve the dispute within the seven (7) day period shall operate as a waiver of this objection, unless the parties agree in writing to extend this deadline while meeting and conferring regarding the objection.

16. **Third Party Vendors.** Counsel may use the services of THIRD PARTY vendors, contractors or agents ("Third Party Vendors") to provide services such as document review, electronic discovery support, computerized legal support, copying and computer services necessary for document handling, other litigation support services (e.g., graphic design and animation, database entry) and management services for the purpose of encoding, loading into a computer and storing and maintaining for information control and retrieval purposes, transcripts of depositions, hearing, trials, pleadings, exhibits marked by any party, briefs and accompanying

affidavits and appendices, documents produced by any party or THIRD PARTY, or a party's own attorney work product, all of which may contain CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

17. **Disclosure to Other Individuals.** Disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION may be made to individuals not identified in ¶¶ 13-14, above, as follows:

a. CONFIDENTIAL INFORMATION may be disclosed to any person not otherwise identified in ¶ 13 above as agreed by the party that designated such information CONFIDENTIAL.

b. HIGHLY CONFIDENTIAL INFORMATION may be disclosed to any person not otherwise identified in ¶ 14 above as agreed by the party that designated such information HIGHLY CONFIDENTIAL.

c. Any party may move the Court, in accordance with the procedures set forth in the Court's Rule 16 Scheduling Order for resolution of discovery disputes, for an Order that a person not identified in ¶ 13 or ¶ 14 above be given access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, respectively, after first signing an Undertaking in the form of Exhibit A attached hereto. Counsel for the moving party shall retain the original of each such signed Undertaking and must include such Undertaking with the parties' motion to the Court.

d. CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION of a producing party may also be disclosed to and/or used to examine, at deposition and at trial (or other court hearing): (i) an individual who either prepared, received or reviewed the CONFIDENTIAL INFORMATION or HIGHLY

CONFIDENTIAL INFORMATION prior to filing of this Action or previously had access or knowledge of the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, as demonstrated on the face of the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION itself or by foundation testimony elicited during a deposition or at trial; (ii) a currently employed officer, employee or expert of a producing party, and/or; (iii) a witness designated for the producing party under Federal Rule 30(b)(6) concerning any topic to which the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is relevant. This Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored or previously had access to or knowledge of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

18. **Confidentiality of Party's Own Documents.** A party may disclose or use in any manner or for any purpose, any information or documents from that party's own files that the party itself has designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

19. **Inadvertent Disclosure.** If CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is disclosed or comes into the possession of any person not authorized to receive such information under this Protective Order, the party responsible for the disclosure shall: (a) within seven (7) days of becoming aware of such disclosure inform the designating party of all pertinent facts relating to such disclosure, including the identity of the person to whom the inadvertent disclosure was made; (b) use its best efforts to obtain the prompt return of the original and all copies of any such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and to bind such unauthorized person or party to the terms of

this Protective Order; (c) within seven (7) days of becoming aware of such disclosure, inform such unauthorized person or party of all provisions of this Protective Order; and (d) request such unauthorized person or party to sign the Undertaking in the form attached hereto as Exhibit A. The executed Undertaking shall be served upon counsel of record for the producing party within seven (7) days of its execution by the person or party to whom CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION was disclosed. The requirements set forth in this Paragraph shall not prevent the producing party from applying to the Court for further or additional relief.

20. **Filing Under Seal.** Any information designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, if filed with the Court in connection with this Action, shall be filed under seal in accordance with the Local Rules or practice of the court in which the information is filed and shall be marked in the caption that the material is being filed under seal such as shown below:

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (MN)
	)	
AVADEL PHARMACEUTICALS PLC,	)	
AVADEL US HOLDINGS, INC., AVADEL	)	<b>Filed Under Seal</b>
SPECIALTY PHARMACEUTICALS, LLC,	)	<b>[Confidential / Highly Confidential]</b>
AVADEL LEGACY PHARMACEUTICALS,	)	<b>Information</b>
LLC, AVADEL MANAGEMENT	)	
CORPORATION and AVADEL CNS	)	
PHARMACEUTICALS LLC,	)	
	)	
Defendants.	)	

[Description of Contents]

In addition, any document that is to be filed with the Court and that contains or discloses CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall be marked “FILED UNDER SEAL” on its cover page. Material designated filed under seal shall be maintained in such manner as provided for by the Court. However, the burden of proving that such document should be sealed shall at all times remain on the party that designated the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION contained in the document.

21. **Challenging Designations.** The acceptance by any party of material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not constitute an admission or concession, or permit an inference that such material is appropriately designated. Any receiving party may at any time request that the designating party cancel or modify the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION designation with respect to any document, object or information. Such request shall be made to counsel for the designating party in writing, and shall particularly identify the designated CONFIDENTIAL INFORMATION OR HIGHLY CONFIDENTIAL INFORMATION that the receiving party contends is not CONFIDENTIAL or HIGHLY CONFIDENTIAL, as the case may be, and the reasons supporting its contention. If the designating party does not agree to remove the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION designation within fourteen (14) days after receipt of such a request, then the party contending that such documents or material are not CONFIDENTIAL or HIGHLY CONFIDENTIAL may request by motion that the Court remove such material from the restrictions of this Protective Order, in accordance with the procedures set forth in the Court’s Rule 16 Scheduling Order for resolution of discovery disputes. On such a motion, the party asserting confidentiality shall have the burden

of proving that the material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION warrants protection under this Protective Order.

22. **No Expansion of Federal Rules of Civil Procedure.** Nothing in this Protective Order shall be construed to be an implied admission or to affect or govern the scope of discovery in this Action, or to preclude any party from moving the Court for a further order pursuant to Fed. R. Civ. P. 26(c), or any other provision of the Federal Rules of Civil Procedure. Nothing contained in this Protective Order shall be construed to require production or disclosure of any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION deemed by counsel for the party possessing such material to be protected from disclosure by the attorney-client privilege or the attorney work-product immunity, or other privilege or immunity, so long as the withheld materials are identified in the manner required by the Federal Rules of Civil Procedure by the producing party. However, this Protective Order shall not prevent the parties from agreeing that certain categories of documents need not be identified, nor shall it prevent one or more parties from seeking relief from the Court if, *e.g.*, identification of individual documents would be unduly burdensome. This Protective Order shall not preclude any party from moving the Court for an order compelling production or disclosure of such material.

23. **New parties to this Action.** In the event additional parties join or are joined in this Action, they shall not have access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION until the newly joined party or its counsel has executed and, at the request of any party, filed with the Court its agreement to be fully bound by this Protective Order or an alternative protective order is agreed to by all parties and entered by the Court.

24. **Miscellaneous.** This Protective Order shall not be construed to prevent any of the parties, or any THIRD PARTY, from applying to the Court for relief or further or additional

protective orders, or from agreeing between or among themselves to modifications of this Protective Order, subject to the approval of the Court. The Protective Order shall not preclude the parties from enforcing their rights against any THIRD PARTY not associated with this Action who is believed to be violating their rights.

25. **Other Proceedings.** By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION pursuant to this order shall promptly notify that party of the motion in writing so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

26. **Publicly Available Information.** This Protective Order shall not apply to any information of the parties which: (a) the producing or designating party or parties agree(s) should not be designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION; (b) the producing or designating party or parties agree(s), or the Court rules, is already public knowledge; (c) the producing or designating party or parties agree(s), or the Court rules, has become public knowledge other than as a result of disclosure by the receiving party, its employees or agents in violation of this Protective Order; or (d) the producing or designating party or parties agree(s), or the Court rules, has come or shall come into the receiving party's legitimate knowledge or possession independently of the producing party under conditions such that its use and/or public disclosure by the receiving party would not violate any obligation to an opposing party to this Action. The restrictions and obligations set forth herein shall not prohibit discussions



of any material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION with any person who already has or obtains legitimate possession thereof.

27. **Survival of Obligations under Protective Order.** With respect to any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, this Protective Order shall survive the final termination of this Action to the extent the information in such material is not or does not become known to the public and continues to be binding upon all persons to whom CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is disclosed hereunder. Upon final termination of this Action, each outside litigation firm listed herein for each party may retain one copy of the case file, including pleadings or other papers filed with the Court or served in the course of the litigation, deposition transcripts, deposition exhibits, the trial record, legal memoranda, correspondence, expert reports, attorney work product, consultant and expert work product, and exhibits to any of these materials, even if such materials reflect materials designated under this Protective Order.

Within sixty (60) calendar days after final termination of this Action, including all appeals, however, all other copies and samples of material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and any other summaries, abstracts, excerpts, indices and descriptions of such material, and information derived from such material that are recorded in any tangible form, shall be: (i) assembled and returned (except for any that may be retained by the Court) to the producing party; or, alternatively, (ii) counsel for the receiving party may certify in writing the destruction thereof. Accordingly, upon final termination of this Action, no one other than the each outside litigation firm listed herein per party shall retain any copies or samples of any material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. As to CONFIDENTIAL INFORMATION or HIGHLY

CONFIDENTIAL INFORMATION stored in computer databases or backup tapes or disks, the receiving party shall either (1) delete all such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, (2) restrict access to such material with passwords, or (3) designate the information CONFIDENTIAL or HIGHLY CONFIDENTIAL in a manner reasonably calculated to prevent unauthorized access to the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

In the event that there are multiple parties, final termination of this Action shall be deemed to occur when the case is terminated and all appeals, or the time for such appeals, has been completed.

The Court retains jurisdiction even after the termination of the Action to enforce this Order and to make such amendments, modifications, deletions and additions to this Order as the Court may deem appropriate.

28. **Waiver or Termination of Order.** No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for each designating party, or by an Order of the Court for good cause shown. The restrictions provided for herein shall not terminate upon the conclusion of this action, but shall continue until further Order of this Court. The termination of employment of any person with access to any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not relieve such person from the obligation of maintaining the confidentiality of such information.

29. **Modification of Order; Prior Agreements.** This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties without further Order of the Court. This Protective Order supersedes any agreements between the parties

regarding the confidentiality of particular information entered into before the date of this Protective Order.

30. **Section Captions.** The title captions for each section of this Protective Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

31. **Notice.** Notice under this Protective Order shall be to the parties as follows, unless this provision is modified by the parties in writing and filed with this Court: notice to Jazz Pharmaceuticals shall be made to F. Dominic Cerrito (nickcerrito@quinnemanuel.com), Quinn Emanuel Urquhart & Sullivan, LLP, 51 Madison Avenue, New York, NY 10010; notice to Avadel shall be made to Kenneth G. Schuler (kenneth.schuler@lw.com), Latham & Watkins LLP, 330 North Wabash Avenue, Suite 2800, Chicago, IL 60611 and Daralyn Durie (ddurie@durietangri.com), Durie Tangri LLP, 217 Leidesdorff Street, San Francisco, CA 94111.

32. **Order Applicable Upon Filing with the Court.** Upon filing this Protective Order with the Court, the parties agree to treat it as “So Ordered,” subject to any future modifications by agreement of the parties or by the Court.

MORRIS, NICHOLAS, ARSHT & TUNNELL LLP

*/s/ Jeremy A. Tigan*

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Jack B. Blumenfeld (#1014)  
Jeremy A. Tigan (#5239)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jblumenfeld@morrisnichols.com  
jtigan@morrisnichols.com

MCCARTER & ENGLISH, LLP

*/s/ Daniel M. Silver*

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Daniel M. Silver (#4758)  
Alexandra M. Joyce (#6423)  
Renaissance Centre  
405 N. King Street, 8th Floor  
Wilmington, DE 19801  
(302) 984-6300  
dsilver@mccarter.com  
ajoyce@mccarter.com

OF COUNSEL:

F. Dominic Cerrito  
Eric C. Stops  
Evangeline Shih  
Andrew S. Chalson  
Gabriel P. Brier  
Frank C. Calvosa  
QUINN EMANUEL URQUHART & SULLIVAN LLP  
51 Madison Avenue, 22nd Floor  
New York, NY 10010  
(212) 849-7000

*Attorneys for Plaintiff  
Jazz Pharmaceuticals, Inc.*

OF COUNSEL:

Kenneth G. Schuler  
Marc N. Zubick  
Alex Grabowski  
Sarah W. Wang  
LATHAM & WATKINS LLP  
330 North Wabash Avenue, Suite 2800  
Chicago, IL 60611  
(312) 876-7700

Herman Yue  
Bornali Rashmi Borah  
LATHAM & WATKINS LLP  
1271 Avenue of the Americas  
New York, NY 10020  
(212) 906-1200

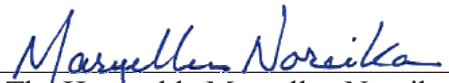
Daralyn J. Durie  
DURIE TANGRI LLP  
217 Leidesdorff Street  
San Francisco, CA 94111  
(415) 365-6666

Kira A. Davis  
Katherine E. McNutt  
DURIE TANGRI LLP  
953 East 3rd Street  
Los Angeles, CA 90013  
(213) 992-4499

*Attorneys for Defendants Avadel  
Pharmaceuticals plc, Avadel US Holdings,  
Inc., Avadel Specialty Pharmaceuticals, LLC,  
Avadel Legacy Pharmaceuticals, LLC, Avadel  
Management Corporation, and Avadel CNS  
Pharmaceuticals LLC*

August 18, 2021

It is SO ORDERED this 19th day of August 2021.

  
\_\_\_\_\_  
The Honorable Maryellen Noreika  
United States District Judge

# EXHIBIT A

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (MN)
	)	
AVADEL PHARMACEUTICALS PLC,	)	
AVADEL US HOLDINGS, INC., AVADEL	)	
SPECIALTY PHARMACEUTICALS, LLC,	)	
AVADEL LEGACY PHARMACEUTICALS,	)	
LLC, AVADEL MANAGEMENT	)	
CORPORATION and AVADEL CNS	)	
PHARMACEUTICALS LLC,	)	
	)	
Defendants.	)	

**UNDERTAKING OF \_\_\_\_\_**

I, \_\_\_\_\_, declare under penalty of perjury that:

1. My present address is \_\_\_\_\_.
2. My present employer is \_\_\_\_\_, and the address of my present employer is \_\_\_\_\_.
3. My present occupation is \_\_\_\_\_.
4. I have received a copy of the Protective Order in this Action. I have carefully read and understand the provisions of the Protective Order. Specifically, I understand that I am obligated, under order of the Court, to hold in confidence and not disclose the contents of anything marked CONFIDENTIAL or HIGHLY CONFIDENTIAL to anyone other than the persons permitted by paragraphs 13-14 of the Protective Order. I further understand that I am not to disclose to anyone other than the persons permitted by paragraph 13 of the Protective Order any words, substances, copy, summary, abstract, excerpt, index, or description of any CONFIDENTIAL INFORMATION disclosed to me, and that I am not

to disclose to anyone other than the persons permitted by paragraph 14 of the Protective Order any words, substances, copy, summary, abstract, excerpt, index, or description of any HIGHLY CONFIDENTIAL INFORMATION disclosed to me.

5. I will comply with all provisions of the Protective Order and hereby submit to the jurisdiction of the United States District Court for the District of Delaware for the purpose of the enforcement of the Protective Order in this Action.
6. I will destroy or return all CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION that comes into my possession, and all documents and things that I have prepared relating thereto, to counsel for the party by whom I am employed or retained or from whom I received such material at the termination of this action or at any time when requested to do so. I acknowledge that return or destruction of such materials shall not relieve me from any of the continuing obligations imposed upon me by the Protective Order.
7. I understand that if I violate the provisions of the Protective Order, I will be subject to sanctions by the Court and that one or more of the parties may seek other remedies against me. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of the Protective Order in this Action.

I declare under penalty of perjury of the laws of the United States (28 U.S.C. § 1746) that the foregoing is true and correct.

Dated: \_\_\_\_\_

\_\_\_\_\_  
Signature