

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.)	

[PROPOSED] SCHEDULING ORDER

This _____ day of _____, 2021, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b) on July 30, 2021, and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS HEREBY ORDERED that:

1. Rule 26(a)(1) Initial Disclosures and E-Discovery Default Standard.

Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within five (5) days of the date this Order is entered by the Court. If they have not already done so, the parties are to review the Court’s Default Standard for Discovery, Including Discovery of Electronically Stored Information (“ESI”), which is posted at <http://www.ded.uscourts.gov> (see Other Resources, Default Standard for Discovery) and is incorporated herein by reference.

2. Disclosures

(a) When the U.S. Food and Drug Administration (“FDA”) accepted Defendants’ (“Avadel”) New Drug Application (“NDA”) that is the subject of this lawsuit, it assigned Avadel’s NDA a Prescription Drug User Fee Act (“PDUFA”) target action date of October 15, 2021 by which time the FDA may approve Avadel’s NDA or request additional information. In light of this, and to ensure that the Court has adequate time to consider and rule on any potential preliminary injunction motion, should such a need arise, the parties shall adhere to the following procedures:

(b) Pursuant to the Court’s Order during the July 30, 2021 Rule 16 Conference that Avadel produce its NDA and associated FDA correspondence immediately, Avadel shall produce such documents no later than **August 6, 2021** on an outside counsels’ eyes only basis pursuant to D. Del. LR 26.2, plus one expert who Plaintiff will identify to Avadel prior to any disclosure of Avadel’s confidential information to that expert. Following its initial production, Avadel shall produce a copy of all correspondence between itself and the FDA pertaining to the NDA to Plaintiff no later than seven days after the date that Avadel sends same to the FDA or receives same from the FDA. If Avadel receives a communication from the FDA on the PDUFA target action date of October 15, 2021, it shall produce such FDA communication to Plaintiff no later than **October 17, 2021**.

(c) By **September 7, 2021**, Plaintiff shall serve its infringement contentions containing the information required by ¶ 4(c) of the Delaware Default Standard for Discovery. Avadel shall serve its invalidity contentions containing the information required by ¶ 4(d) of the Delaware Default Standard For Discovery no later than **October 13, 2021**. Plaintiff will provide the Court with a status report by **October 18, 2021** regarding whether preliminary injunction

proceedings may be necessary at that time. If Plaintiff decides to file a motion for a preliminary injunction at this time, it should file its motion by **October 22, 2021**. If Plaintiff files a motion for preliminary injunction on October 22, 2021, Avadel's responsive briefing shall be due **November 5, 2021**, and Plaintiff's reply briefing shall be due **November 12, 2021**. Should Plaintiff file a motion for a preliminary injunction on or before October 22, 2021, a hearing on Plaintiff's motion will be scheduled for **November 23, 2021** at 10:00 am.

(d) In connection with any preliminary injunction briefing and hearing, parties shall be permitted to submit evidence in support or opposition, including but not limited to documentary evidence, expert testimony, and fact witness testimony. Any party submitting witness testimony shall make such witness(es) available for deposition at least two weeks after serving the witness(es)' testimony, and at least two weeks before the opposing parties' next papers are due. Any witness(es) submitted in support of Plaintiff's reply papers shall be made available for deposition at least a week before the oral argument date set by the Court.

(e) In the event preliminary injunction proceedings are begun, the parties reserve the right to seek modification of all dates in the remainder of this schedule, to account for the need to devote resources to the preliminary injunction process. In the event a Party seeks to modify any date in this schedule, that Party shall meet and confer with the other Parties to attempt to reach agreement on any such modification. Any unresolved disputes shall be submitted pursuant to the Court's procedures for resolving discovery disputes.

3. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **November 1, 2021**. Unless otherwise ordered by the Court, any motion to join a party or motion to amend the pleadings shall be made pursuant to the procedures set forth in Paragraphs 8(g) and 9.

4. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within ten (10) days from the date the Court enters this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 8(g) below.

Any proposed protective order must include the following paragraph:

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 information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

5. Papers Filed Under Seal. In accordance with section G of the Revised Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

6. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of all briefs and any other document filed in support of any briefs (*i.e.*, appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

7. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

8. Discovery. Unless otherwise ordered by the Court or agreed to by parties, the limitations on discovery set forth in the Federal Rules shall be strictly observed.

(a) Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before **October 21, 2022**.

(b) Document Production. Document production shall be substantially complete by **April 8, 2022**.

(c) Requests for Admission. A maximum of 100 requests for admission are permitted for each side.

(d) Interrogatories.

i. A maximum of 25 interrogatories, including contention interrogatories, are permitted for each side.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy of all interrogatory answers shall be judged by the level of detail each party provides (*i.e.*, the more detail a party provides, the more detail a party shall receive).

(e) Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of 70 hours of taking testimony by deposition upon oral examination.

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court. A defendant who becomes a

counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.

(f) Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule of Civil Procedure 26(a)(2) disclosure of expert testimony is due on or before **December 16, 2022**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **February 17, 2023**. Reply expert reports from the party with the initial burden of proof are due on or before **April 14, 2023**. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Expert Report Supplementation. The parties agree they will permit expert declarations to be filed in connection with motions briefing (including case-dispositive motions).

iii. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than **July 7, 2023**, unless otherwise ordered by the Court. Briefing will be presented pursuant to the Court's Local Rules.

iv. Expert Discovery Cut Off. All expert discovery in this case shall be initiated so that it will be completed on or before **June 30, 2023**.

(g) Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after a reasonable effort pursuant to Local Rule 7.1.1. that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Judicial Administrator to schedule an argument.

iii. On a date to be set by separate order, generally not less than four (4) days prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than three (3) days prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. The parties shall provide to the Court two (2) courtesy copies of its discovery letter and any other document filed in support of any letter (*i.e.*, appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal. All courtesy copies shall be double-sided.

v. Should the Court find further briefing necessary upon conclusion of the conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the conference and will, in that event, cancel the conference.

9. Motions to Amend / Motions to Strike.

(a) Any motion to amend (including a motion for leave to amend) a pleading or any motion to strike any pleading or other document shall be made pursuant to the discovery dispute procedure set forth in Paragraph 8(g) above.

(b) Any such motion shall attach the proposed amended pleading as well as a “redline” comparison to the prior pleading or attach the document to be stricken.

10. Technology Tutorials. Although technology tutorials are not required by the Court, they are appreciated and, if any party chooses to file such a tutorial, it shall be submitted on or before the date that the Joint Claim Construction Brief is filed.

11. Claim Construction Issue Identification. On **February 25, 2022**, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be submitted two weeks prior to service of the opening claim construction brief. The parties’ Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party’s proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. Intrinsic evidence (including copies of the patent(s) at issue) shall NOT be attached to the joint claim construction chart and, instead, the parties shall include a joint appendix with the joint claim construction brief, and the joint appendix shall include a copy of the patent(s) at issue and portions of all relevant intrinsic evidence that would have otherwise been included with the joint claim construction chart, as well as any additional evidence cited in the parties’ briefing.

12. Claim Construction Briefing. The Plaintiff shall serve, but not file, its opening brief, not to exceed 20 pages, on **April 29, 2022**. The Defendant shall serve, but not file, its answering brief, not to exceed 30 pages, on **May 20, 2022**. The Plaintiff shall serve, but not file, its reply brief, not to exceed 20 pages, on **June 10, 2022**. The Defendant shall serve, but not file,

its sur-reply brief, not to exceed 10 pages, on **June 24, 2022**. No later than **July 1, 2022**, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below. If the joint brief as submitted is more than 80 pages, the parties must certify that the page limits (or equivalent word counts) in the Scheduling Order have been complied with and provide a brief explanation (e.g., formatting issues, listing of agreed-upon terms) as to why the brief is longer than 80 pages.

JOINT CLAIM CONSTRUCTION BRIEF

I. Agreed-Upon Constructions

II. Disputed Constructions

[TERM 1]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

[TERM 2]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

13. Hearing on Claim Construction. Beginning at 10:00 am on **August 2, 2022**, the Court will hear argument on claim construction. The parties need not include any general summaries of the law relating to claim construction in their presentations to the Court. The parties shall notify the Court, by joint letter submission, no later than the date on which their joint claim construction brief is filed: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

14. Supplementation. Absent agreement among the parties, and approval of the Court, no later than **November 18, 2022** the parties must finally supplement, *inter alia*, the identification of all accused products and of all invalidity references.

15. Case Dispositive Motions. The parties shall not file case dispositive motions without leave of Court.

16. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion filed with the Clerk. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

17. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each **SIDE** shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be

supported by a maximum of three (3) pages of argument, may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

18. Pretrial Conference. On **October 23, 2023**, the Court will hold a pretrial conference in Court with counsel beginning at 4:30 pm. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order in compliance with Local Rule 16.3(c) and the Court's Preferences and Procedures for Civil Cases not later than seven (7) days before the pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(3) for the preparation of the joint proposed final pretrial order.

The parties shall provide the Court two (2) double-sided courtesy copies of the joint proposed final pretrial order and all attachments. The proposed final pretrial order shall contain a table of contents and the paragraphs shall be numbered.

19. Trial. This matter is scheduled for a 5 day bench trial beginning at 9:30 a.m. on **October 30, 2023**, with the subsequent trial days beginning at 9:00 a.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

20. Post-Trial Briefing. The parties will address the post-trial briefing schedule and page limits in the proposed final pretrial order.

The Honorable Maryellen Noreika
United States District Judge

Chart of All Relevant Deadlines

EVENT	DEADLINE
Defendants' Production of NDA and Related FDA Correspondence	August 6, 2021
Plaintiff's Infringement Contentions	September 7, 2021
Defendant's Invalidity Contentions	October 13, 2021
Plaintiff's Update to the Court Regarding Whether Preliminary Injunction May be Necessary	October 18, 2021
Plaintiff's Preliminary Injunction Motion (If Necessary)	October 22, 2021
All motions to join other parties, and to amend or supplement the pleadings	November 1, 2021
Defendants' Preliminary Injunction Response (If Necessary)	November 5, 2021
Plaintiff's Preliminary Injunction Reply (If Necessary)	November 12, 2021
Preliminary Injunction Hearing (If Necessary)	November 23, 2021
Identity of claim terms for construction	February 25, 2022
Substantial Completion of Document Discovery	April 8, 2022
Joint Claim Construction Chart	April 15, 2022
Plaintiff's Opening Claim Construction Brief	April 29, 2022
Defendants' Rebuttal Claim Construction Brief	May 20, 2022
Plaintiff's Reply Claim Construction Brief	June 10, 2022
Defendants' Sur-Reply Claim Construction Brief	June 24, 2022
Joint Claim Construction Brief	July 1, 2022
Claim Construction Hearing	August 2, 2022
Fact Discovery Cutoff	October 21, 2022
Final Identification of Accused Product / Invalidity References	November 18, 2022
Opening Expert Reports	December 16, 2022
Rebuttal Expert Reports	February 17, 2023
Reply Expert Reports	April 14, 2023
Expert Discovery Cutoff	June 30, 2023
Daubert Motions	July 7, 2023
Final Pretrial Conference	October 23, 2023
Trial Begins (5 days)	October 30, 2023