

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

REGENXBIO INC. and THE TRUSTEES
OF THE UNIVERSITY OF
PENNSYLVANIA,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,
SAREPTA THERAPEUTICS THREE, LLC,
AND CATALENT INC.,

Defendant.

C.A. No. 23-667-RGA

SCHEDULING ORDER

This 19th day of September, 2023, the Court having waived an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), 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 ORDERED that:

1. Rule 26(a)(1) Initial Disclosures. 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 **30 days** of the date of this Order.
2. 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 **March 15, 2024**.
3. Discovery.
 - a. Discovery Cut Off. All discovery in this case shall be initiated so that it will be completed on or before **December 6, 2024**.

b. Document Production. Document production shall be substantially complete by **August 30, 2024**.

c. Requests for Admission. A maximum of 30 requests for admission are permitted for each side, exclusive of requests for admission to establish the authenticity of documents. There is no limit on the number of requests for admission the parties may serve to establish the authenticity of documents, but the parties will negotiate in good faith to determine a reasonable procedure for serving requests for admission to establish the authenticity of documents to ensure such requests are not unduly burdensome.

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

e. Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of 84 hours of testimony by deposition of fact witnesses upon oral examination, including depositions of third parties (other than experts), with a limit of seven (7) hours per witness.

For expert deposition discovery, each side shall be entitled to a single deposition for each expert, with a limit of seven (7) hours per deposition. If a party believes that additional hours for deposition are necessary, the parties shall meet and confer and try to reach agreement on the amount of additional hours needed, and thereafter, if unable to reach agreement, a party seeking modification of this provision may petition the Court through the Court's discovery dispute resolution procedures.

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 or by agreement of the parties. A defendant who becomes a cross-claimant or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.

f. Discovery Matters and Disputes Relating to Protective Orders. Should counsel find 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 Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than seven business days prior to the conference/argument, any party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than five business days prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's opposition. A party should include with its letter a proposed order with a detailed issue-by-issue ruling such that, should the Court agree with the party on a particular issue, the Court could sign the proposed order as to that issue, and the opposing party would be able to understand what it needs to do, and by when, to comply with the Court's order. Any proposed order shall be e-mailed, in Word format, simultaneously with filing to rga_civil@ded.uscourts.gov.

If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

g. Miscellaneous Discovery Matters.

i. Unless otherwise agreed to by the parties, the parties agree to follow the Court's Default Standard for Discovery. Specifically, the parties agree to the following:

1. The parties agree to make the disclosures required by paragraph 3 of the Default Standard for Discovery for the District of Delaware within 30 days of the date of this order;
2. Plaintiffs shall identify the accused products and make the disclosures required by paragraph 4.a. by **October 11, 2023**;
3. Defendants shall produce core technical documents and make the disclosures required by paragraph 4.b. by **November 8, 2023**;
4. Plaintiffs shall produce its initial claim chart and make the disclosures required by paragraph 4.c. by **December 13, 2023**;
5. Defendants shall produce its initial invalidity contentions and make the disclosures required by paragraph 4.d. by **February 21, 2024**.

ii. Other than this civil action, the patent-in-suit (U.S. Patent No. 11,680,274) has not been subject to litigation or *inter partes* review ("IPR"). Plaintiffs do not expect to institute any further

litigation in this or other Districts within the next year.

Defendants have not decided whether, and if so when, to file an IPR.

- iii. Plaintiffs are complying with the Court's requirement that they file the proposed orders necessary for them to provide notice to their licensees regarding production of any license agreements no later than twenty-four hours before the initial Rule 16 conference.

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 45 days from the date of this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 3(f) above.

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 as confidential 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. When filing papers under seal, a redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

6. Claim Construction Issue Identification. On or before **March 27, 2024**, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction¹. On or before **April 10, 2024**, the parties shall exchange their proposed claim construction of those term(s)/phrase(s). Neither of these documents will be filed with the Court. Subsequent to exchanging this list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than **April 19, 2024**. The Joint Claim Construction Chart, in Word format, shall be e-mailed simultaneously with filing to rga_civil@ded.uscourts.gov. 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. The Joint Claim Construction Chart should include an explanation of why resolution of the dispute makes a difference. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

7. Claim Construction Briefing². Plaintiffs shall serve, but not file, their opening brief, not to exceed 5,000 words, as well as any materials in support of their proposed

¹ If a party proposes a construction of a term to be its "plain and ordinary" meaning, the party must explain what that meaning is. If a term is arguably a means-plus-function term, and a party does not propose a function and a structure, it is waiving any right to propose a function and a structure at a later time.

² As each brief is written and provided to the opposing party, the individual responsible for verifying the word count will represent to the other party that it has so verified and by what means. These verifications should not be provided to the Court unless a dispute arises about them. Pictures, Figures copied from the patent, and other illustrations do not count against the word limit. Plaintiff should include with its opening brief one or more representative claims with the disputed terms italicized. Should Defendants want to add additional representative claims, Defendants may do so. The representative claims and the agreed-upon claim constructions do not count against the word limit.

constructions, including expert declarations, on **May 10, 2024**. Defendants shall serve, but not file, their answering brief, not to exceed 7,500 words, as well as any materials in support of their proposed constructions, including expert declarations, on **June 7, 2024**. Plaintiffs shall serve, but not file, their reply brief, not to exceed 5,000 words, as well as any materials in support of their proposed constructions, including expert declarations, on **June 28, 2024**. Defendants shall serve, but not file their sur-reply brief, not to exceed 2,500 words, as well as any materials in support of their proposed constructions, including expert declarations, on **July 19, 2024**. No later than **July 31, 2024**, 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.

JOINT CLAIM CONSTRUCTION BRIEF

- I. Representative Claims
- II. Agreed-upon Constructions
- III. Disputed Constructions
 - A. [TERM 1]³
 - 1. Plaintiff's Opening Position
 - 2. Defendant's Answering Position
 - 3. Plaintiff's Reply Position
 - 4. Defendant's Sur-Reply Position
 - B. [TERM 2]
 - 1. Plaintiff's Opening Position
 - 2. Defendant's Answering Position
 - 3. Plaintiff's Reply Position
 - 4. Defendant's Sur-Reply Position

Etc. The parties need not include any general summaries of the law relating to claim construction. If

³ For each term in dispute, there should be a table or the like setting forth the term in dispute and the parties' competing constructions. The table does not count against the word limits.

there are any materials that would be submitted in an appendix, the parties shall submit them in a Joint Appendix.

8. Hearing on Claim Construction. Beginning at 9:00 a.m. on **August 22, 2024**, the Court will hear argument on claim construction. Absent prior approval of the Court (which, if it is sought, must be done so by joint letter submission no later than the date on which answering claim construction briefs are due), the parties shall not present testimony at the argument, and the argument shall not exceed a total of three hours. When the Joint Claim Construction Brief is filed, the parties shall simultaneously file a motion requesting the above-scheduled claim construction hearing, state that the briefing is complete, and state how much total time the parties are requesting that the Court should allow for the argument.

9. Disclosure of Expert Testimony.

a. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before **January 22, 2025**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **February 26, 2025**. Reply expert reports from the party with the initial burden of proof are due on or before **March 26, 2025**. No other expert reports will be permitted without either the consent of all parties or leave of the Court. If any party believes that an expert report does not comply with the rules relating to timely disclosure or exceeds the scope of what is permitted in that expert report, the complaining party must notify the offending party within one week of the submission of the expert report. The parties are expected to promptly try to resolve any such disputes, and, when they cannot reasonably be resolved, use the Court's Discovery Dispute Procedure or the

complaint will be waived.

Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition. Depositions of experts shall be completed on or before **May 9, 2025**.

b. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than the deadline for dispositive motions set forth herein, unless otherwise ordered by the Court.

10. Case Dispositive Motions. All case dispositive motions, an opening brief, and affidavits, if any, in support of the motion shall be served and filed on or before **June 4, 2025**. Responsive briefs shall be served and filed on or before **July 2, 2025**. Reply briefs shall be served and filed on or before **July 25, 2025**. No case dispositive motion under Rule 56 may be filed more than ten days before the above date without leave of the Court. Absent an order of the Court upon a showing of good cause, each side is limited to one forty-page opening brief, one forty-page answering brief, and one twenty-page reply brief for all of its Daubert and case dispositive motions.

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

12. Pretrial Conference. On **November 7, 2025**, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at 9:00 a.m.. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on

the fourth business day before the date of the final pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

13. Motions in Limine. Motions *in limine* shall be separately filed, with each motion containing all the argument described below in one filing for each motion. Any supporting documents in connection with a motion *in limine* shall be filed in one filing separate from the motion *in limine*. Each party shall be limited to three *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 pages of argument and may be opposed by a maximum of three pages of argument, and the party making the *in limine* request may add a maximum of one 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 page submission (and, if the moving party, a single one page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

14. Jury Instructions, Voir Dire, and Special Verdict Forms. Where a case is to be tried to a jury, pursuant to Local Rules 47.1(a)(2) and 51.1, the parties should file (i) proposed voir dire, (ii) preliminary jury instructions, (iii) final jury instructions, and (iv) special verdict forms no later than 6 p.m. on the fourth business day before the date of the final pretrial conference. Areas of dispute shall be identified as narrowly as possible and in a manner that makes it readily apparent what the dispute is. The parties shall submit simultaneously with filing each of the foregoing four documents in Word format to rga_civil@ded.uscourts.gov.

15. Trial. This matter is scheduled for a five (5) day jury trial beginning at 9:30 a.m. on **November 17, 2025**, with the subsequent trial days beginning at 9:30 a.m. Until the case is submitted to the jury for deliberations, the jury will be excused each day at 5:00 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

16. Mediation (for use in non-ANDA patent cases). The Parties are required to engage in good faith in an in-person mediation. They are to hire a jointly agreed-upon mediator. The timing of mediation efforts is left to the discretion of the Parties, but the mediation efforts need to be conducted in advance of the pretrial conference. The Parties are required to submit a joint statement no later than one week before the pretrial conference. The joint statement is to include the identification of the mediator, the lead counsel for each party at the mediation, the length of the mediation, and the certification of the lead mediation counsel that they have engaged in the efforts in good faith. If the Parties anticipate any further efforts by the mediator at the time of the submission, they should so advise. The joint statement should not disclose the substance of any offers, counter-offers, or other negotiations.

/s/ Richard G. Andrews

UNITED STATES DISTRICT JUDGE