IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REGENXBIO INC. and THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,	)	
Plaintiffs,	)	C.A. No. 23-667 (RGA)
v.	)	**JURY TRIAL DEMANDED**
SAREPTA THERAPEUTICS, INC., SAREPTA THERAPEUTICS THREE, LLC, and CATALENT INC.	)	
Defendants.	)	

DEFENDANTS SAREPTA THERAPEUTICS, INC. AND SAREPTA THERAPEUTICS THREE, LLC'S ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT AND FOR DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

Defendants Sarepta Therapeutics, Inc. and Sarepta Therapeutics Three, LLC, (collectively, "Sarepta"), by and through their undersigned counsel, hereby submit their Answer to the Complaint for Patent Infringement and for Declaratory Judgment of Patent Infringement ("Complaint") (D.I. 1) filed by RegenxBio Inc. ("Regenx") and The Trustees of The University of Pennsylvania ("UPenn") (collectively, "Plaintiffs") as follows:

NATURE OF ACTION[1]

1. Sarepta admits that the Complaint purports to be an action for infringement of United States Patent No. 11,680,274 ("the '274 patent") instituted under the Patent Laws of the United States, 35 U.S.C. §§ 271 (a)-(c), and for a declaratory judgment of infringement of the '274 patent under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Sarepta admits

[1] For convenience and clarity, Sarepta's Answer uses the same headings as the Complaint. Sarepta does not admit any allegations contained in the Complaint's headings.

that the Complaint alleges that Sarepta infringes the '274 patent through its alleged manufacture and use of an adeno-associated virus ("AAV") technology gene therapy product, referred to as SRP-9001. Sarepta denies that it has infringed any claim of the '274 patent or that the claims of the '274 patent are valid. Sarepta admits that SRP-9001 is in continuing clinical trials for the treatment of Duchenne muscular dystrophy ("DMD"), and that on June 22, 2023, SRP-9001 was approved by the United States Food and Drug Administration ("FDA") for the treatment of ambulatory pediatric patients aged 4 through 5 years with DMD with a confirmed mutation of the DMD gene. Sarepta admits that Exhibit A purports to be a copy of the '274 patent. Sarepta denies any remaining allegations in Paragraph 1.

THE PARTIES

2. Upon information and belief, Sarepta admits the allegations of Paragraph 2.

3. Upon information and belief, Sarepta admits the allegations of Paragraph 3.

4. Upon information and belief, Sarepta admits the allegations of Paragraph 4.

5. Sarepta denies that Regenx's NAV® Technology Platform is entitled to patent protection. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

6. Sarepta admits that Sarepta Therapeutics, Inc., is a corporation organized under the laws of the State of Delaware and has a registered agent located at 251 Little Falls Drive, Wilmington, Delaware. Sarepta admits that Sarepta Therapeutics, Inc. has a place of business at 215 First St., Cambridge, MA 02142. Sarepta denies any remaining allegations in Paragraph 6.

7. Sarepta admits that Sarepta Therapeutics Three, LLC is a wholly-owned subsidiary of Sarepta Therapeutics, Inc. Sarepta admits that Sarepta Therapeutics Three, LLC is a limited liability company organized under the laws of the State of Delaware and has a registered agent

located at 251 Little Falls Drive, Wilmington, Delaware. Sarepta admits that Sarepta Therapeutics Three, LLC has a place of business at 215 First St., Cambridge, MA 02142. Sarepta denies any remaining allegations in Paragraph 7.

8. Sarepta admits that Sarepta Therapeutics, Inc., is a global biopharmaceutical company focused on helping patients through the discovery and development of unique RNA-targeted therapeutics, gene therapy, and other genetic therapeutic modalities for the treatment of rare diseases. Sarepta denies any remaining allegations in Paragraph 8.

9. Sarepta admits that Sarepta Therapeutics Three, LLC is a wholly-owned subsidiary of Sarepta Therapeutics, Inc. that is involved in contracting related to SRP-9001. Sarepta denies any remaining allegations in Paragraph 9.

10. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

11. Sarepta admits that Catalent manufactures SRP-9001. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the remaining matters asserted in this paragraph and therefore denies them.

12. Sarepta admits it is not a party to any license agreement with Regenx and/or UPenn. Sarepta denies that it needs a license to the ’274 patent to conduct its business. Sarepta denies any remaining allegations in Paragraph 12.

JURISDICTION AND VENUE

13. Paragraph 13 contains a legal conclusion to which no response is required. To the extent a response is required, Sarepta admits that Plaintiffs have brought an action arising under the patent laws of the United States, Title 35, of the United States Code. Sarepta denies that this Court has subject matter jurisdiction over Plaintiffs’ claims directed to any of Sarepta’s activities

that have been solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. To the extent Plaintiffs' claims are directed to Sarepta's activities that are protected by the Safe Harbor provision of 35 U.S.C. § 271(e)(1), the Court lacks subject matter jurisdiction. Sarepta denies any remaining allegations in Paragraph 13.

14. Paragraph 14 contains a legal conclusion to which no response is required. To the extent a response is required, Sarepta admits that Plaintiffs have brought an action arising under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States for a declaratory judgment. Sarepta denies that this Court has subject matter jurisdiction over Plaintiffs' claims directed to any of Sarepta's activities that have been solely for uses reasonably related to the development and submission of information to the FDA. To the extent Plaintiffs' claims are directed to Sarepta's activities that are protected by the Safe Harbor provision of 35 U.S.C. § 271(e)(1), the Court lacks subject matter jurisdiction. Sarepta denies any remaining allegations in Paragraph 14.

15. Paragraph 15 contains a legal conclusion to which no response is required. To the extent a response is required, Sarepta admits that venue is proper in this District for purposes of this action only. Sarepta denies any remaining allegations in Paragraph 15.

16. Paragraph 16 contains a legal conclusion to which no response is required. To the extent a response is required, Sarepta admits that this Court has personal jurisdiction over Sarepta Therapeutics, Inc., for purposes of this action only. Sarepta denies any remaining allegations in Paragraph 16.

17. Paragraph 17 contains a legal conclusion to which no response is required. To the extent a response is required, Sarepta admits that this Court has personal jurisdiction over Sarepta

Therapeutics Three, LLC for purposes of this action only. Sarepta denies any remaining allegations in Paragraph 17.

18. Paragraph 18 contains a legal conclusion to which no response is required. To the extent a response is required, Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

19. Paragraph 19 contains a legal conclusion to which no response is required. To the extent a response is required, Sarepta admits that this Court has personal jurisdiction over Sarepta Therapeutics, Inc. and Sarepta Therapeutics Three, LLC for purposes of this action only. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the remaining matters asserted in this paragraph and therefore denies them.

FACTUAL BACKGROUND

Background Technology

20. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

21. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

22. Paragraph 22 contains a legal conclusion to which no response is required. To the extent a response is required, Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

The Patent-in-Suit

23. Sarepta admits that the ’274 Patent is titled “Method of Increasing the Function of an AAV Vector.” Sarepta admits that the ’274 Patent on its face lists June 20, 2023 as the issue date. Sarepta admits that the ’274 Patent on its face names Luk Vandenberghe, Guangping Gao,

and James M. Wilson as inventors. Sarepta admits that the '274 Patent on its face names The Trustees of the University of Pennsylvania as the assignee. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the remaining matters asserted in this paragraph and therefore denies them.

24. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

25. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

26. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

27. Sarepta denies that it has infringed any claim of the '274 patent or that the claims of the '274 patent are valid. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

28. Sarepta denies that it has infringed any claim of the '274 patent or that the claims of the '274 patent are valid. Sarepta is without knowledge or information sufficient to form a belief as to the truth of the matters asserted in this paragraph and therefore denies them.

Count I
(Infringement of the '274 Patent)

29. Sarepta restates as if fully set forth herein each of the foregoing paragraphs.

30. Sarepta denies the allegations in Paragraph 30.

31. Sarepta denies the allegations in Paragraph 31.

32. Sarepta denies the allegations in Paragraph 32.

33. Sarepta denies the allegations in Paragraph 33.

34. Sarepta denies the allegations in Paragraph 34.

35. Sarepta denies the allegations in Paragraph 35.

36. Sarepta denies the allegations in Paragraph 36.

37. Sarepta denies the allegations in Paragraph 37.

38. Sarepta admits that, on September 28, 2022, Sarepta Therapeutics, Inc. submitted a BLA to the FDA for accelerated approval of SRP-9001, and that the FDA accepted the BLA for filing on November 25, 2022. Sarepta admits that on June 22, 2023, SRP-9001 was approved by the FDA for the treatment of ambulatory pediatric patients aged 4 through 5 years with DMD with a confirmed mutation of the DMD gene. Sarepta denies the remaining allegations in Paragraph 38.

39. Sarepta admits that Sarepta Therapeutics Three, LLC has entered into an agreement with F. Hoffman-La Roche Ltd. ("Roche") concerning rights to SRP-9001 outside the United States. Sarepta admits that Sarepta has performed its contractual obligations under the Roche agreement. Sarepta admits that Roche has registered a clinical trial involving SRP-9001 with the EU Clinical Trials Register. Sarepta denies the remaining allegations in Paragraph 39.

40. Sarepta denies the allegations in Paragraph 40.

41. Sarepta admits that it became aware of the '274 patent no later than the date of filing of the Complaint. Sarepta denies the remaining allegations in Paragraph 41.

42. Sarepta denies the allegations in Paragraph 42.

43. Sarepta denies the allegations in Paragraph 43.

44. Sarepta denies the allegations in Paragraph 44.

Count II
(Declaratory Judgment of Infringement of the '274 Patent)

45. Sarepta restates as if fully set forth herein each of the foregoing paragraphs.

46. Sarepta denies the allegations in Paragraph 46.

47. Sarepta denies the allegations in Paragraph 47.

48. Sarepta admits that it has registered two global clinical trials involving SRP-9001 with the EU Clinical Trials Register. Sarepta denies the remaining allegations in Paragraph 48.

49. Sarepta admits that, on September 28, 2022, Sarepta Therapeutics, Inc. submitted a BLA to the FDA for accelerated approval of SRP-9001, and that the FDA accepted the BLA for filing on November 25, 2022. Sarepta admits that on June 22, 2023, SRP-9001 was approved by the FDA under the tradename ELEVIDYS™ for the treatment of ambulatory pediatric patients aged 4 through 5 years with DMD with a confirmed mutation of the DMD gene. Sarepta denies the remaining allegations in Paragraph 49.

50. Sarepta denies the allegations in Paragraph 50.

51. Paragraph 51 states a request for relief to which no response is required. To the extent a response is required, Sarepta denies the allegations in Paragraph 51.

JURY TRIAL DEMAND

Sarepta admits that Plaintiffs have demanded a jury trial pursuant to Federal Rule of Civil Procedure 38(b) but denies that they are entitled to one.

PRAYER FOR RELIEF

Sarepta denies that Plaintiffs are entitled to the relief requested or to any other relief.

Sarepta denies all allegations of the Complaint not specifically admitted above.

DEFENSES

By alleging the Defenses set forth below, Sarepta does not agree or concede that it bears the burden of proof or the burden of persuasion on any of these issues, whether in whole or in part. For its Defenses to the Complaint, Sarepta alleges as follows:

FIRST DEFENSE
(Non-Infringement)

Sarepta has not infringed and is not infringing any claim of the ’274 patent, either literally or under the doctrine of equivalents.

SECOND DEFENSE
(Safe Harbor)

Sarepta’s activities are immune or otherwise protected from suit under the Safe Harbor provision of 35 U.S.C. § 271(e)(1), which states that “[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . . .”

THIRD DEFENSE
(Prosecution History Estoppel)

The ’274 patent is limited by amendment, the prior art and/or statements made during its prosecution before the United States Patent and Trademark Office such that Plaintiffs are now estopped and/or otherwise precluded from maintaining that such claims of the ’274 patent are of sufficient scope to cover the products accused of infringement in this case, either literally or under the doctrine of equivalents.

FOURTH DEFENSE
(Prosecution Laches)

The ’274 patent is unenforceable due to the unreasonable and unexplained delay in prosecution of the ’274 patent resulting in prejudice to Sarepta.

FIFTH DEFENSE
(Equitable Estoppel)

Plaintiffs’ claims for relief are barred in whole or in part by the doctrine of equitable estoppel.

SIXTH DEFENSE
(Invalidity)

The ’274 patent is invalid for failure to comply with the conditions of patentability, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112.

SEVENTH DEFENSE
(Double Patenting)

The ’274 patent is invalid for obviousness-type double patenting.

EIGHTH DEFENSE
(No Injunctive Relief)

Plaintiffs are not entitled to injunctive relief because any alleged injury to Plaintiffs is neither immediate nor irreparable, Plaintiffs have an adequate remedy at law, and the public interest is not served by the granting of an injunction.

NINTH DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief may be granted.

TENTH DEFENSE
(Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction over the Complaint to the extent Plaintiffs’ claims are directed to Sarepta’s activities that are protected by the Safe Harbor provision of 35 U.S.C. § 271(e)(1).

ELEVENTH DEFENSE
(No Damages)

Plaintiffs have incurred no damages as a result of the alleged infringement, which Sarepta denies.

RESERVATION OF ADDITIONAL DEFENSES

Sarepta reserves any and all additional defenses available under Title 35 of the United States Code, or otherwise in law or equity, now existing, or later arising, as may be discovered.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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August 10, 2023

CERTIFICATE OF SERVICE

I hereby certify that on August 10, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 10, 2023, upon the following in the manner indicated:

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