IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REGENXBIO INC. and THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, Plaintiffs, v. SAREPTA THERAPEUTICS, INC., SAREPTA THERAPEUTICS THREE, LLC, AND CATALENT INC. Defendants.	CASE NO. _____ JURY TRIAL DEMAND

COMPLAINT FOR PATENT INFRINGEMENT AND FOR DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

REGENXBIO Inc. and The Trustees of the University of Pennsylvania (collectively "Plaintiffs"), by and through their undersigned attorneys, bring this action against Defendants Sarepta Therapeutics, Inc. ("Sarepta Inc.") and Sarepta Therapeutics Three, LLC ("Sarepta Three") (together, "Sarepta"), and Catalent Inc. ("Catalent"), and hereby allege as follows:

NATURE OF ACTION

1. This is 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, arising from Defendants' manufacture, use, and imminent commercial launch of an adeno-associated virus ("AAV") technology gene therapy product that is claimed in the '274 Patent that Defendants refer to as "SRP-9001 (AAVrh74.MHCK.micro-

dystrophin)," which is used to treat Duchenne muscular dystrophy ("DMD"). A true and accurate copy of the '274 Patent is attached as Exhibit A.

THE PARTIES

2. Plaintiff the Trustees of the University of Pennsylvania ("University") is a nonprofit corporation organized and existing under the laws of the State of Pennsylvania, with a place of business at 1 College Hall, Philadelphia, Pennsylvania 19104.

3. University is an institution of higher education and academic research and an academic medical center.

4. Plaintiff REGENXBIO Inc. (formerly ReGenX) ("REGENXBIO") is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 9804 Medical Center Drive, Rockville, MD 20850.

5. REGENXBIO is a clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. REGENXBIO focuses on developing treatments for diseases with significant unmet needs, such as retinal, metabolic, and neurodegenerative diseases, using its patented NAV® Technology Platform, which includes, *inter alia*, the '274 Patent. In addition to its own programs in neurodegenerative and neuromuscular diseases, REGENXBIO has licensed many third parties under the NAV® patents in these disease areas.

6. Upon information and belief, Defendant Sarepta Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 215 First St., Cambridge, MA 02142.

7. Upon information and belief, Defendant Sarepta Three is a wholly-owned subsidiary of Sarepta Inc. Upon further information and belief, Sarepta Three is a company

organized and existing under the laws of the State of Delaware, with a principal place of business at 215 First St., Cambridge, MA 02142.

8. Upon information and belief, Sarepta Inc. is a biotechnology company in the business of, among other activities, developing products using AAV technology to treat diseases.

9. Upon information and belief, Sarepta Three is an entity involved in the commercialization and manufacture of products in collaboration with Sarepta Inc., including in the United States.

10. Upon information and belief, Catalent is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 14 Schoolhouse Road, Somerset, NJ 08873.

11. Upon information and belief, Catalent is a company in the business of, among other activities, manufacturing and supplying patient therapies in the United States including Sarepta's gene therapies using AAV technology to treat disease.

12. Upon information and belief, the AAV technology of the '274 Patent is being used by Defendants without a license for, *inter alia*, manufacturing, and preparing to commercialize at least Sarepta's SRP-9001 product.

JURISDICTION AND VENUE

13. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, including §§ 271(a), 271(b), and 271(c). This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

14. This is an action also 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 that Defendants' imminent actions will infringe the '274 Patent.

15. Venue is proper in this district under 28 U.S.C. § 1400(b) and/or 28 U.S.C. §§ 1391(b) and (c).

16. This Court has personal jurisdiction over Sarepta Inc. as it is a corporation organized and existing under the laws of the State of Delaware, and since it has availed itself of the rights and benefits of Delaware law, it should reasonably anticipate being haled into court in this judicial district.

17. This Court has personal jurisdiction over Sarepta Three as it is a corporation organized and existing under the laws of the State of Delaware, and since it has availed itself of the rights and benefits of Delaware law, it should reasonably anticipate being haled into court in this judicial district.

18. This Court has personal jurisdiction over Catalent as it is a corporation organized and existing under the laws of the State of Delaware, and since it has availed itself of the rights and benefits of Delaware law, it should reasonably anticipate being haled into court in this judicial district.

19. On information and belief, Defendants have established, and will continue to maintain, minimum contacts with this judicial district such that the exercise of jurisdiction over Defendants would not offend traditional notions of fair play and substantial justice.

FACTUAL BACKGROUND

Background Technology

20. Genetic changes ─ mutations or deletions in one's DNA ─ can cause serious disease or other metabolic dysfunctions that adversely impact health. People affected by such genetic changes face chronic disease and often require expensive medications to control their symptoms. Gene therapy offers a revolutionary alternative: a chance to treat the underlying cause

of the symptoms by delivering a therapeutic gene, known as a "transgene," that corrects the course of disease and potentially provides lasting results from a single therapeutic dose.

21. Gene therapy can involve the use of a "vector" that packages and delivers a transgene into the body's cells. REGENXBIO has exclusive license rights to vectors invented at University, known as NAV® Vectors, composed of "capsid proteins" that package the transgene used to treat genetic defects or supply therapeutic factors such as antibodies to treat other serious conditions. Upon administration to a patient, the recombinant vectors deliver the transgenes to the nucleus of affected cells. Once there, transgenes serve as a genetic blueprint for new proteins that supply the function needed to treat or cure disease.

22. The claimed subject matter of the '274 Patent, discussed *infra,* is an adeno-associated virus comprising an AAV capsid and a minigene. It can be used in the process of delivering a transgene into cells in animal laboratory studies, or to deliver the transgene into cells in human subjects. The AAV vectors claimed in the '274 Patent have unique properties, *e.g.*, an ability to target certain types of cells in the body.

The Patent-in-Suit

23. The '274 Patent is entitled "Method of Increasing the Function of an AAV Vector," issued on June 20, 2023, names Luk Vandenberghe, Guangping Gao, and James M. Wilson as inventors, and was assigned to University.

24. On May 31, 2002, University granted GlaxoSmithKline LLC ("GSK") an exclusive world-wide right and license, with the right to grant sublicenses, to various intellectual property

rights, including predecessor applications to the application that issued as the ’274 Patent. Under that license agreement, GSK was also given the right to prosecute infringement claims.

25. On February 24, 2009, subject to certain limitations relating to the patents licensed to GSK, University granted ReGenX (now REGENXBIO) an exclusive world-wide right and license, with the right to grant sublicenses, to various intellectual property rights, including the predecessor applications to the application that issued as ’274 Patent. Under that license agreement, REGENXBIO was also given the right to prosecute infringement claims, including for the predecessor applications to the application that issued as ’274 Patent.

26. On March 6, 2009, GSK granted ReGenX (now REGENXBIO) an exclusive world-wide right and license, with the right to grant sublicenses, to various intellectual property rights, including the predecessor applications to the application that issued as ’274 Patent. Under that license agreement, REGENXBIO was also given the right to prosecute infringement claims, including for the predecessor applications to the application that issued as ’274 Patent.

27. GSK subsequently assigned to REGENXBIO any claims that GSK has arising from past, present, or future infringement of any claim in the predecessor applications to the application that issued as ’274 Patent by Sarepta.

28. Plaintiffs collectively have all substantial rights in and to the ’274 Patent, including the right to assert any claims for the past, present, and future infringement of the ’274 Patent against Sarepta.

Count I
(Infringement of the ’274 Patent)

29. Plaintiffs reallege paragraphs 1-28 as if fully set forth herein.

30. On information and belief, Defendants' manufacture and use of SRP-9001 practices the patented AAV technology claimed in the '274 Patent prior to the expiration of the '274 Patent and constitutes direct infringement under 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, of at least one claim of the '274 Patent.

31. On information and belief, each of the Defendants infringe, directly under 35 U.S.C. § 271(a), and/or indirectly under 35 U.S.C. §§ 271(b) or (c), at least claim 1 of the '274 Patent, which recites in full:

> 1. A recombinant adeno-associated virus (AAV) comprising an AAV capsid and a minigene having AAV inverted terminal repeats and a heterologous gene operably linked to regulatory sequences which direct expression of the heterologous gene in a host cell, wherein the AAV capsid comprises AAV vp1 proteins, AAV vp2 proteins, and AAV vp3 proteins, wherein the AAV vp1 proteins have i) the sequence of amino acids 1 to 738 of SEQ ID NO: 4 (AAVrh46), or ii) an amino acid sequence at least 95% identical to the full length of amino acids 1 to 738 of SEQ ID NO: 4, wherein the amino acid residue corresponding to position 665 in SEQ ID NO: 4 is N when aligned along the full length of amino acids 1 to 738 of SEQ ID NO: 4.

32. Upon information and belief, Defendants have made and used SRP-9001 in the United States, which is a recombinant adeno-associated virus comprising an AAV capsid and a minigene having AAV inverted terminal repeats and a heterologous gene operably linked to regulatory sequences which direct expression of the heterologous gene in a host cell, wherein the AAV capsid comprises AAV vp1 proteins, AAV vp2 proteins, and AAV vp3 proteins, wherein the AAV vp1 proteins have i) the sequence of amino acids 1 to 738 of SEQ ID NO: 4 (AAVrh46), or ii) an amino acid sequence at least 95% identical to the full length of amino acids 1 to 738 of SEQ ID NO: 4, wherein the amino acid residue corresponding to position 665 in SEQ ID NO: 4 is N when aligned along the full length of amino acids 1 to 738 of SEQ ID NO: 4.

33. Upon information and belief, SRP-9001 is an AAV gene therapy product that uses an AAVrh74 capsid protein to package and deliver a transgene. Upon information and belief, the AAVrh74 vector has vp1, vp2, and vp3 capsid proteins, with the vp1 capsid protein having an amino acid sequence at least 95% identical to the full length of amino acids 1 to 738 of SEQ ID NO: 4 (AAVrh46), and the amino acid residue corresponding to position 665 in SEQ ID NO: 4 is N. (Ex. B (Nationwide Children's Hospital ("Nationwide") patent filing providing the amino acid sequence of the capsid protein of AAVrh74 at SEQ ID NO: 2); Ex. C (Nationwide Sequence Listing for WO 2013/078316); Ex. D (January 10, 2017, press release announcing agreement between Sarepta and Nationwide regarding a microdystrophin gene therapy program for treatment of DMD).)

34. With regard to the entities that engage in such making and using, upon information and belief, that entity is either Sarepta Inc. and/or Sarepta Three, or an agent and/or contractual partner of either or both Sarepta Inc. and/or Sarepta Three, such as Catalent, which make and use the AAV technology gene therapy product claimed in the '274 Patent in the United States. Thus, upon information and belief, each of Sarepta Inc., Sarepta Three, and/or Catalent directly infringes at least claim 1 of the '274 Patent under 35 U.S.C. § 271(a) to the extent they make and use the AAV technology gene therapy product claimed in the '274 Patent. (*See, e.g.*, Ex. E, Sarepta Sept. 30, 2022 Form 10-Q, at 27 ("We have adopted a hybrid development and manufacturing strategy in which we have built internal process development expertise relative to all aspects of AAV-based manufacturing, including gene therapy and gene editing supply, while closely partnering with first-in-class manufacturing partners to expedite development and commercialization of our gene therapy programs."); Ex. F, Catalent Press Release, Jan. 5, 2023 (announcing "the signing of a commercial supply agreement for Catalent to manufacture delandistrogene moxeparvovec (SRP-

9001), Sarepta's most advanced gene therapy candidate for the treatment of Duchenne muscular dystrophy (DMD)" and noting "Catalent will be Sarepta's primary commercial manufacturing partner for this therapy."); Ex. G, www.catalent.com (accessed Feb. 2, 2023) (Catalent webpage displaying "Sarepta and Catalent expand strategic manufacturing partnership with commercial supply agreement for Duchenne muscular dystrophy gene therapy candidate").)

35. Additionally or alternatively, upon information and belief, Sarepta Inc. and/or Sarepta Three instructs and/or contracts with at least Thermo Fisher Scientific Inc. ("Thermo"), Catalent, and others to make and use the AAV technology gene therapy product claimed in the '274 Patent. (*See, e.g.*, Ex. F, Catalent Press Release, Jan. 5, 2023 (Sarepta noting it is "excited to strengthen and expand our relationship with Catalent to meet anticipated demand for SRP-9001"); Ex. H, Sarepta Press Release, Jan. 5, 2023 (same); Ex. I, Sarepta Company Conference Presentation, Sept. 12, 2022, at 8 ("[O]ur primary supplier -- our sole supplier at time of launch will be Catalent."); *id*. ("We can launch and fully serve the launch in the U.S. and Europe and other select countries in Japan out of the Catalent facilities, we've taken enough suites."); Ex. E, Sarepta Sept. 30, 2022 Form 10-Q, at 27 ("Our gene therapy manufacturing capabilities have been greatly enhanced through partnerships with Thermo Fisher Scientific Inc. ("Thermo"), Catalent, Inc. ("Catalent"). . . We expect that our partnerships with Thermo and Catalent will support our clinical and commercial manufacturing capacity for our SRP-9001 Duchenne program and LGMD programs, while also acting as a manufacturing platform for potential future gene therapy programs. The collaboration integrates process development, clinical production and testing, and commercial manufacturing.").) Sarepta Inc. and/or Sarepta Three thus actively induce such infringement by their partners, such as Catalent, under 35 U.S.C. § 271(b).

36. On information and belief, Sarepta and/or Catalent, and/or Sarepta's and/or Catalent's contractual partners at the direction of Sarepta and/or Catalent, have manufactured and are continuing to build a commercial stock of SRP-9001 in the United States for use in the United States and abroad, in violation of Plaintiffs' patent rights. (*See, e.g.*, Ex. I, Sarepta Company Conference Presentation, Sept. 12, 2022, at 9 ("[W]e feel very comfortable about where we are and our ability to -- we're going to build a bunch of inventory between now and this year and the launch."); Ex. J, Sarepta FQ3 2022 Earnings Call, Nov. 2, 2022, at 17 ("Are you in good shape from a capacity perspective to fully launch? And the answer is yes, we're going to be in very good shape. We're planning to launch for the ambulatory patient population. That is our current working assumption, broadly speaking, and our goal is to fully serve that community without delay."); Ex. K, Evercore ISI HealthCONx Conference, Dec. 1, 2022, at 7 ("We're building inventory even as we speak"); Ex. E, Sarepta Sept. 30, 2022 Form 10-Q, at 26 ("For our commercial Duchenne program, we have worked with our existing CMOs to increase product capacity from mid-scale to large-scale."); Ex. L, JP Morgan Healthcare Conference, Jan. 9, 2023, at 3 ("And in fact, all of our assays for commercial release of this therapy are completed, and we're building launch inventory as we speak right now.").)

37. On information and belief, Sarepta and/or Catalent, and/or Sarepta's and/or Catalent's contractual partners at the direction of Sarepta and/or Catalent are building a commercial stock of SRP-9001 in the United States for uses not reasonably related to the development and submission of information to a regulatory agency in the United States. (*See, e.g.*, Ex. I, Sarepta Company Conference Presentation, Sept. 12, 2022, at 9 ("[F]rom a launch readiness perspective, and site readiness perspective, we want to have 70. So our goal right now is to have 70 sites expert and ready to go at launch to support the launch.").)

38. On information and belief, Sarepta has applied for FDA regulatory approval of SRP-9001, and imminently expects to commercially launch its infringing SRP-9001 gene therapy product in the United States upon receiving FDA approval. (Ex. M, Sarepta Press Release re FDA Filing, Nov. 28, 2022, ("[T]he U.S. Food and Drug Administration (FDA) has accepted the Company's Biologics License Application (BLA) seeking accelerated approval of SRP-9001 (delandistrogene moxeparvovec) for the treatment of ambulant individuals with Duchenne muscular dystrophy. SRP-9001 has been granted Priority Review by the FDA, with a regulatory action date of May 29, 2023.").)

39. Upon information and belief, Sarepta has partnered with Roche to develop and market SRP-9001 outside the United States. (Ex. M, Sarepta Press Release re FDA Filing, Nov. 28, 2022 ("SRP-9001 is an investigational gene therapy for Duchenne being developed in partnership with Roche."); Ex. N, Roche Press Release, Dec. 23, 2019 ("Roche obtains the exclusive right to launch and commercialize SRP-9001, Sarepta's investigational micro-dystrophin gene therapy for Duchenne muscular dystrophy (DMD) outside the United States.").) Upon further information and belief, and pursuant to an agreement between Sarepta and Roche, Sarepta instructs its contractual partners such as Catalent to manufacture the SRP-9001 product in the United States for use by Roche abroad. (*See, e.g.*, Ex. E, Sarepta September 30, 2022 Form 10-Q at 50 (Sarepta noting it has "limited influence and control over the development and commercialization activities of Roche in the territories in which it leads development and commercialization of SRP-9001")). Upon information and belief, Roche has initiated clinical trials outside of the United States using SRP-9001 manufactured inside the United States. (*See, e.g.*, Ex. O, EU Clinical Trials Register, EudraCT Number 2022-000691-19, accessed Jan. 23,

2023 (indicating Roche obtaining supply of SRP-9001 from Sarepta for clinical trial in Spain with planned sites in Belgium, France, Germany, Italy, Spain, and the U.K.).)

40. Moreover, on information and belief, to the extent Defendants supply others with components (such as plasmids encoding the AAVrh74 capsid protein), which have no substantially non-infringing uses, Defendants contribute to such infringement under 35 U.S.C. § 271(c).

41. Defendants became aware of the ’274 Patent no later than the date of filing of this Complaint. As a result, the use of the AAV technology gene therapy product claimed in the ’274 Patent for the production of SRP-9001 was made and will be made with full knowledge of the ’274 Patent and without a reasonable basis for believing that Defendants would not be liable for infringing or actively inducing or contributing to the infringement of the ’274 Patent.

42. Defendants have engaged in deliberate and willful behavior with knowledge of the ’274 Patent and knew or should have known that its actions constituted direct and/or indirect infringement of the ’274 Patent.

43. The making and using of SRP-9001 using the AAV technology gene therapy product claimed in the ’274 Patent in violation of Plaintiffs’ patent rights will cause harm to Plaintiffs for which damages are inadequate.

44. Unless and until Defendants are enjoined from directly and/or indirectly infringing the ’274 Patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

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

45. Plaintiffs reallege paragraphs 1-44 as if fully set forth herein.

46. As discussed above in paragraphs 1-44, each of Sarepta Inc., Sarepta Three, and Catalent infringes, directly under 35 U.S.C. § 271(a), and/or indirectly under 35 U.S.C. §§ 271(b) or (c), at least claim 1 of the ’274 Patent.

47. On information and belief, Sarepta and/or Catalent, and/or Sarepta’s and/or Catalent’s contractual partners at the direction of Sarepta and/or Catalent, have manufactured and are continuing to build a commercial stock of SRP-9001 in the United States for use in the United States and abroad, in violation of Plaintiffs’ patent rights. (*See* ¶¶ 36, 37).

48. On information and belief, Sarepta has instituted clinical trials outside of the United States using SRP-9001 manufactured inside the United States. (*See* Ex. P, EU Clinical Trials Register, EudraCT Number: 2019-003374-91, accessed Jan. 23, 2023 (indicating Sarepta sponsored SRP-9001 clinical trial sites in Belgium, France, Germany, Hong Kong, Italy, Japan, Spain, Taiwan, and the U.K.); Ex. Q, EU Clinical Trials Register, EudraCT Number: 2020-002372-13, accessed Jan. 23, 2023 (indicating Sarepta sponsored SRP-9001 clinical trial sites in Australia, Belgium, France, Germany, Israel, Italy, Japan, Spain, Sweden, and the U.K.).)

49. Further on information and belief, Sarepta has applied for FDA regulatory approval of SRP-9001, and imminently expects to commercially launch its infringing SRP-9001 gene therapy product in the United States upon receiving FDA approval. (*See* ¶ 38).

50. An actual and justiciable case or controversy exists between Plaintiffs and Defendants as to the infringement of the ’274 Patent, as evidenced by Plaintiffs’ Complaint, and by Defendants’ actions to build commercial stock of the infringing SRP-9001 product in the United States, and Defendants’ intention to launch the infringing SRP-9001 product for sale in the United States upon receiving FDA regulatory approval, as set forth above. Absent a declaration of infringement, Defendants will imminently commence sales of the infringing SRP-9001 product in

the United States upon receiving FDA regulatory approval and will continue their manufacture of SRP-9001 in the United States for use in clinical trials outside the United States in violation of Plaintiffs' '274 Patent, thereby causing Plaintiffs irreparable injury and damage.

51. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Plaintiffs request a declaration of the Court that Defendants' imminent commercial launch of the SRP-9001 product will infringe at least claim 1 of the '274 Patent, either directly, contributorily, or by inducement.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Sarepta Inc., Sarepta Three, and/or Catalent has infringed the '274 Patent by making and/or using the infringing SRP-9001 product in violation of the '274 Patent in the United States and/or by actively inducing and/or contributing to such infringement;

b. That the Court declare and enter judgment that Defendants' imminent commercial launch of its infringing SRP-9001 product in the United States will infringe the '274 Patent;

c. That the Court grant equitable relief that it deems appropriate, including that Plaintiffs reserve the right to seek that an injunction be issued permanently enjoining Sarepta Inc., Sarepta Three, and/or Catalent and their affiliates, officers, agents, employees, attorneys, and all persons in active concert or participation with any of them, from infringing the '274 Patent, from manufacturing or using the AAV technology gene therapy product claimed in the '274 Patent, and

from offering for sale or selling any such product prior to the expiration of the ’274 Patent, if and only if another gene therapy for DMD becomes available;

d. That Plaintiffs be awarded damages adequate to compensate them for the past, present, and/or future infringement of the ’274 Patent by Defendants, said damages being no less than a reasonable royalty together with any pre-judgment and post-judgment interest as allowed by law, costs, and other damages permitted by 35 U.S.C. § 284;

e. A judgment finding that Defendants’ infringement of the ’274 Patent was deliberate and willful;

f. That an accounting be performed to determine the damages to be awarded to Plaintiffs as a result of Defendants’ infringing activities, including an accounting for infringing conduct not presented at trial and an award of additional damages for any such infringing sales;

g. An award to Plaintiffs of costs and expenses they incur in prosecuting this action; and

h. That this Court award such other and further relief as it may deem just and proper.

Dated: June 20, 2023

FISH & RICHARDSON P.C.

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