IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION, Plaintiff, v. SAREPTA THERAPEUTICS, INC., and SAREPTA THERAPEUTICS THREE, LLC. Defendants.	)	C.A. No. _____ JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Genzyme Corporation ("Genzyme"), by and through its undersigned attorneys, bring this action against Defendants Sarepta Therapeutics, Inc. ("Sarepta Therapeutics"), and Sarepta Therapeutics Three, LLC ("Sarepta Three") (together "Sarepta").

NATURE OF ACTION

1. This is an action for infringement of United States Patent Nos. 9,051,542 (the "'542 Patent") and 7,704,721 (the "'721 Patent") (collectively, "the Patents-In-Suit") arising from Defendants' manufacture and sale of Elevidys® (delandistrogene moxeparvovec-rokl), a gene therapy for the treatment of a neuromuscular disease known as Duchenne muscular dystrophy ("DMD"). This action is based upon the Patent Laws of the United States, 35 U.S.C. §§ 100, *et seq.* True and correct copies of the '542 Patent and the '721 Patent are attached as Exhibit A and Exhibit B, respectively.

PARTIES

2. Plaintiff Genzyme is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, having its principal place of business at 450 Water Street, Cambridge, MA 02141. Genzyme is the owner of the '542 Patent and the '721 Patent.

3. Genzyme and its affiliates focus on the development of specialty treatments for debilitating diseases that are often difficult to diagnose and treat.

4. On information and belief, Defendant Sarepta Therapeutics is a company organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 215 First St., Cambridge, MA 02142. On information and belief, Sarepta Therapeutics has a registered agent for service of process, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808.

5. On information and belief, Defendant Sarepta Three is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 215 First St., Cambridge, MA 02142. On information and belief, Sarepta Three has a registered agent for service of process, Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808. On information and belief, Sarepta Therapeutics is the direct or indirect parent of Sarepta Three and has at all times directed and controlled the infringing actions of its subsidiary.

6. On information and belief, Sarepta Therapeutics is a biopharmaceutical company in the business of, among other activities, developing gene therapy products using adeno-associated virus ("AAV") technology to treat diseases, and Sarepta Three is engaged in the commercialization and/or manufacture of biopharmaceutical products in collaboration with Sarepta Therapeutics.

JURISDICTION AND VENUE

7. 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). This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

8. Venue is proper in this district pursuant to 28 U.S.C. § 1400(b) and/or 28 U.S.C. §1391(b) and (c) for at least the reason that each Defendant resides in this district.

9. This Court has personal jurisdiction over Sarepta Therapeutics and Sarepta Three because they are incorporated in Delaware, knowingly transact business in Delaware, maintain a registered agent in Delaware, avail themselves of the rights and benefits of Delaware law, and, on information and belief, have engaged in, and made meaningful preparations to engage in, infringing conduct in Delaware.

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

FACTUAL BACKGROUND

Gene Therapy Technology

11. It has long been recognized that certain diseases are caused by missing or defective genes, resulting in the inability of the body to produce key proteins. The result can be devastating, but the options for treating such genetic diseases have been limited. The radical approach taken by gene therapy is to attack the problem at the source—the patient's own genome—by providing a working copy of a defective or missing gene with what is referred to as a transgene. Gene therapy is at the cutting edge of medical technology, and the problems faced both in the delivery of transgenes and their manufacture are daunting.

12. Gene therapy can be performed by taking advantage of one of the body's age-old enemies, viruses, which have evolved to enter human cells. By removing part of the native viral DNA and substituting the DNA of the desired human transgene, a recombinant virus can be created that can enter cells and then deliver a desired human gene into a cell. At the time of the

inventions of the ’542 Patent and the ’721 Patent, it was known that in the right circumstances a modified adeno-associated virus (“AAV”) could be used to achieve the delivery of the transgene. These genetically-engineered versions of the AAV are known as recombinant AAV (“rAAV”) vectors.

13. Manufacturing rAAV-based therapeutics is a highly technical, multi-phase process involving rAAV vector production, which includes the creation of the vector genome, or genetic payload carrying the transgene, encapsulation of the vector genome in a protein shell called a capsid, followed by purification and formulation. A major concern during production is that the rAAV vector particles will become insoluble and aggregate into clusters of viral particles, which can result in production difficulties and loss of vector functionality. Low solubility and aggregation are problems thought to be attributable to the highly symmetrical nature of rAAV vector particles in conjunction with the stabilizing effect of complementary charged regions between neighboring particles in aggregates. Filtration can remove these aggregates during the purification process but at the cost of significantly reducing viral vector yields and thus increasing production costs.

14. Aggregation is particularly problematic with respect to formulations that are administered in ultraconcentrated, small volumes, as the high concentration levels promote aggregation. In such cases, aggregation can negatively impact the effectiveness of treatment, as well as increase the chance of an immune reaction following administration.

15. The inventions described in the ’542 Patent and the ’721 Patent are directed towards solving these problems. John Fraser Wright and Guang Qu, the inventors of the subject matter claimed in the ’542 Patent and the ’721 Patent, discovered that the use of certain high ionic strength solutions for preparing and storing rAAV vectors can prevent significant aggregation

of virus particles at the concentrations needed for effective gene therapy. They invented rAAV formulations and related methods in which vector particles remain soluble when elevated ionic strengths are used during purification and for final vector formulation.

The Patents-in-Suit

The ’542 Patent

16. On June 9, 2015, the United States Patent & Trademark Office (“USPTO”) duly and legally issued the ’542 Patent, titled “Compositions and Methods to Prevent AAV Vector Aggregation.” The ’542 Patent is assigned to Genzyme. A true and correct copy of the ’542 Patent is attached as Exhibit A.

17. The claims of the ’542 Patent are generally directed to the preparation of high ionic strength compositions for the storage of purified, rAAV vector particles in which the vector particles do not significantly aggregate. On June 15, 2023, Genzyme statutorily disclaimed claims 1 and 2 of the ’542 Patent. Claims 3-6 of the ’542 Patent expire on June 1, 2025.

The ’721 Patent

18. On April 27, 2010, the USPTO duly and legally issued the ’721 Patent, titled “Compositions and Methods to Prevent AAV Vector Aggregation.” The ’721 Patent is assigned to Genzyme. A true and correct copy of the ’721 Patent is attached as Exhibit B.

19. The claims of the ’721 Patent are generally directed to methods for the preparation of high ionic strength compositions for the storage of purified, rAAV vector particles in which the vector particles do not significantly aggregate. The claims of the ’721 Patent expire on June 1, 2025.

Elevidys®

20. Sarepta Therapeutics is the holder of Biologics License Application ("BLA") No. 125781 for Elevidys® (delandistrogene moxeparvovec-rokl) (also referred to as "SRP-9001"). Elevidys® is a onetime rAAV gene therapy product that is used to treat certain patients with DMD. A true and correct copy of the current Elevidys® package insert, dated June 2024, is attached as Exhibit C.

21. DMD is a form of muscular dystrophy caused by a mutation in the DMD gene that renders patients unable to produce a functional dystrophin protein. The disease typically strikes young boys around the age of four and leads to progressive muscle weakness. Patients with DMD experience various physical symptoms, including but not limited to, frequent falls, difficulty rising from a lying or sitting position, trouble running and jumping, waddling gait, and muscle pain and stiffness. By adolescence, many patients lose the ability to walk.

22. Elevidys® is designed to deliver the gene encoding a micro-dystrophin protein in the subject's muscle cells. On information and belief, the micro-dystrophin protein is a shortened, but functional, version of the dystrophin protein, comprising only selected domains and a fraction of the molecular weight of the dystrophin protein that is normally expressed in skeletal muscle cells. Elevidys® uses a non-replicating, rAAV vector of the serotype rh74 ("rAAVrh74") capsid to package and deliver a human micro-dystrophin transgene under the control of the MHCK7 promoter. *See* Exhibit C, § 11 Description.

23. On June 22, 2023, Sarepta obtained FDA approval to market Elevidys® for the treatment of ambulatory pediatric patients aged 4 through 5 years with DMD with a confirmed mutation in the DMD gene. *See* Exhibit D, Accelerated BLA Approval. On or about June 20, 2024, Sarepta subsequently obtained FDA approval for an expanded indication for Elevidys®

that significantly broadened the population of eligible patients to include DMD patients four years of age and older who are ambulatory and have a confirmed mutation in the DMD gene and DMD patients four years of age and older who are non-ambulatory and have a confirmed mutation in the DMD gene. *See* Exhibit E, June 20, 2024, Supplement Approval.

24. On information and belief, Sarepta has entered into agreements with Catalent, Inc. and/or Catalent Maryland, Inc. (collectively, "Catalent"), encompassing process development, clinical production and testing, and commercial manufacturing of Elevidys® for the U.S. market. *See* Sarepta Therapeutics, Inc., Annual Report (Form 10-K) p. 10 (Feb. 28, 2024), https://www.sec.gov/Archives/edgar/data/873303/000095017024022036/srpt-20231231.htm ("Sarepta 2024 Form 10-K") . On information and belief, Catalent manufactures the Elevidys® drug substance on behalf of Sarepta in Harmans, MD and the finished drug product in Baltimore, MD. *See* Exhibit F, § 3.2.A, Facilities Table. On information and belief, Elevidys® is manufactured by Catalent on Sarepta's behalf and under Sarepta's direction and control as the BLA holder. On information and belief, Catalent has been manufacturing Elevidys® on Sarepta's behalf, and Defendants have been marketing Elevidys® in the United States since obtaining FDA approval in 2023. *See* Exhibit D, Accelerated BLA Approval. On information and belief Defendants have formed a joint enterprise with Catalent for the manufacture and sale of Elevidys®.

COUNT I
INFRINGEMENT OF THE '542 PATENT

25. Plaintiff repeats and realleges the allegations set forth in paragraphs 1 through 24 above as though fully set forth herein.

26. Plaintiff has all substantial rights in and to the '542 Patent, including the right to assert any claims for past, present, and future infringement of the '542 Patent against Defendants.

27. Defendants have infringed at least one claim of the '542 Patent by making, using, offering for sale, and/or selling Elevidys® in the United States in violation of 35 U.S.C. § 271(a), (b) and (c).

28. The '542 Patent has one independent claim 1, which, as of June 15, 2023, has been statutorily disclaimed. Claims 3 and 6 each depends from claim 1, and thus incorporate all the limitations of claim 1. Claim 1 recites:

> A composition for the storage of purified, recombinant adeno-associated virus (AAV) vector particles, comprising:
>
> > purified, recombinant AAV vector particles at a concentration exceeding 1×10^{13} vg/ml up to 6.4×10^{13} vg/ml;
> >
> > a pH buffer, wherein the pH of the composition is between 7.5 and 8.0; and
> >
> > excipients comprising one or more multivalent ions selected from the group consisting of citrate, sulfate, magnesium, and phosphate; wherein the ionic strength of the composition is greater than 200 mM, and wherein the purified AAV vector particles are stored in the composition without significant aggregation.

29. Elevidys® is a pharmaceutical composition for the storage of purified, rAAV vector particles, employing a "serotype rh74 (AAVrh74) based vector containing the ELEVIDYS micro-dystrophin transgene under the control of the MHCK7 promoter." Exhibit C, § 11 Description. Elevidys® has a "nominal concentration of 1.33 x 10^{13} vg/mL," which is within the claimed range of 1×10^{13} vg/ml up to 6.4×10^{13} vg/ml. Exhibit C, § 11 Description.

30. Elevidys® contains a pH buffer, which is a combination of tromethamine HCl and tromethamine, and wherein the pH of the composition, which can be calculated from its

components, is between 7.5 and 8.0. Exhibit C, § 11 Description ("Each vial [of Elevidys®] contains an extractable volume of 10 mL and the following excipients: 200 mM sodium chloride, 13 mM tromethamine HCl, 7 mM tromethamine, 1 mM magnesium chloride, 0.001% poloxamer 188.").

31. The excipients in Elevidys® comprise the multivalent ion selected from the claimed group, magnesium in the form of magnesium chloride, wherein the ionic strength of the composition is greater than 200 mM.

32. On information and belief, Elevidys® is also stored in the composition without significant aggregation. *See* Exhibit G, § 3.2.P.3.2 Batch Formula (Defendants represented to the FDA that the drug product "[v]ials found to have defects, including visible particles are removed."); *id.*, § 3.2.P.5. Control of Drug Product (The Elevidys® drug product release specifications require the analytical testing of certain attributes of the final drug product before it is permitted to enter the market, including the testing of "Particulate Matter." The FDA reviewer commented that this attribute had "[a]cceptable compendial limits."); *id.*, § 3.2.P.2.6 Compatibility ("According to the Applicant, low levels of visible particles were observed in SRP-9001 drug product vials during the 100% visual inspection process in some batches and were rejected."). On information and belief, the FDA would not approve the product if it failed to meet this requirement.

33. Claim 3 depends from claims 1 and 2 and therefore incorporates all of the limitations of claims 1 and 2. Claims 2 and 3 recite:

> 2. The composition of claim 1, further comprising ethylene oxide/propylene oxide block copolymer Pluronic® F68.
>
> 3. The composition of claim 2, wherein the Pluronic® F68 is present at a concentration of 0.001% (w/v).

34. Elevidys® contains ethylene oxide/propylene oxide block copolymer Pluronic® F68, also known as poloxamer, in the amount of 0.001%. *See* Exhibit C, § 11 Description ("Each vial [of Elevidys®] contains . . . 0.001% poloxamer 188.").

35. Claim 6 depends from claim 1 and recites:

> 6. The composition of claim 1, wherein recovery of the purified, recombinant virus particles is at least about 90% following filtration of the composition of said AAV vector particles through a 0.22 μm filter.

36. On information and belief, the recovery of the purified, recombinant virus particles of Elevidys® is at least about 90% following filtration of the Elevidys® composition through a 0.22 μm filter. The manufacturing process for Elevidys® includes sterile filtration. Exhibit G, § 10.A EXECUTIVE SUMMARY, at p. iv. On information and belief, the sterile filtration is 0.22 μm filter. *See also* Exhibit C, § 2.4 Administration ("Recommended supplies and materials: Syringe infusion pump, 0.2 micron PES* in-line filter, PVC* (non-DEHP*), polyurethan IV infusion tubing and catheter); Exhibit G, § 3.2.P.2.6 Compatibility ("A study to assess the in-use compatibility and effectiveness of a 0.2 μm in-line filter as part of DP administration to remove potential intrinsic particulates in the [drug product], was conducted. . . ."). On information and belief, the yield of Elevidys® following sterile filtration would be within plus or minus 10% of the FDA approved drug product specification (i.e., at least 90%).

37. Defendants' manufacture, sale, offer for sale, and use of the patented compositions in Elevidys® claimed in the '542 Patent prior to the expiration of the '542 Patent constitutes direct infringement under 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, of at least claims 3 and 6 of the '542 Patent.

38. Defendants jointly infringe the '542 Patent by contracting with Catalent to manufacture Elevidys® under the direction and under the control of Sarepta, and/or by forming

a joint enterprise with manufacturers including Catalent for the manufacture of Elevidys®. *See, e.g.*, Sarepta Therapeutics, Inc., Quarterly Report (Form 10-Q) p. 22 (May 1, 2024), https://www.sec.gov/Archives/edgar/data/873303/000095017024051234/srpt-20240331.htm ("Sarepta May 2024 10-Q") ("We have adopted a hybrid development and manufacturing strategy in which we have built internal expertise relative to all aspects of AAV-based manufacturing . . . while closely partnering with experienced manufacturing partners to expedite development and commercialization of our gene therapy programs. We have secured manufacturing capacity at Thermo and Catalent to support our clinical and commercial manufacturing demand for ELEVIDYS and our LGMD programs."); Exhibit H, Catalent Jan. 5, 2023 Press Release at pp. 1-2 ("Catalent will be Sarepta's primary commercial manufacturing partner for this therapy [Elevidys®]."); Exhibit F, § 3.2.A Facilities Table (The Elevidys® drug substance and drug product are manufactured in Catalent facilities in Harmans, MD and Baltimore, MD, respectively). On information and belief, Defendants condition receipt of contractual benefits by Catalent upon manufacture of Elevidys®, and establish the manner and timing of Catalent's performance.

39. Defendants have infringed the '542 Patent by selling and offering to sell Elevidys® to third parties. *See, e.g.*, Exhibit D, June 22, 2023, Accelerated BLA Approval Letter (issuing "U.S. License No. 2308 to Sarepta Therapeutics, Inc." which "authorizes you to introduce or deliver for introduction into interstate commerce" Elevidys®.); Sarepta 2024 Form 10-K at p. 8 ("We launched ELEVIDYS in the second quarter of 2023."); *id.* at p. 76 (Sarepta recorded more than $200 million in revenue from U.S. sales of Elevidys® in 2023 alone.)

40. On information and belief, at least as of the date of the complaint, the Defendants have actively induced infringement of one or more claims of the '542 Patent, including but not

limited to claims 3 and 6, under 35 U.S.C. § 271(b), by providing the infringing product to third parties along with a label providing instructions for use with patients, with knowledge of the '542 Patent and that the induced acts would constitute infringement.

41. Moreover, on information and belief, Defendants contribute to infringement of the '542 Patent, including but not limited to claims 3 and 6, under 35 U.S.C. § 271(c) by supplying components of the claimed compositions, such as the provision of engineered rAAV particles for formulation into finished drug product, such components having no substantially non-infringing uses, with knowledge of the '542 Patent and its infringement at least as of the date of the complaint.

42. Plaintiff has suffered damages as a result of Defendants' infringement of the '542 Patent.

COUNT II
INFRINGEMENT OF THE '721 PATENT

43. Plaintiff repeats and realleges the allegations set forth in paragraphs 1 through 42 above as though fully set forth herein.

44. Plaintiff has all substantial rights in and to the '721 Patent, including the right to assert any claims for past, present, and future infringement of the '721 Patent against Defendants.

45. Defendants have infringed at least one claim of the '721 Patent by making, using, offering for sale, and/or selling Elevidys® in the United States in violation of 35 U.S.C. § 271(a), (b) and (c).

46. The '721 Patent has one independent claim 1. Claim 1 recites:

> A method of preventing aggregation of recombinant adeno-associated virus (rAAV) virions in a purified preparation of rAAV virions, comprising:

> 1) providing a lysate comprising rAAV virions;
>
> 2) purifying rAAV virions from the lysate using ultracentrifugation and/or chromatography, wherein said virions are purified; and
>
> 3) adding one or more salts of multivalent ions selected from the group consisting of citrate, phosphate, sulfate and magnesium to said purified virions to produce a preparation of virions with an ionic strength of at least 200 mM, wherein the concentration of purified rAAV virions in said preparation exceeds 1×10^{13} vg/ml up to 6.4×10^{13} vg/ml; and wherein the pH of the purified preparation of rAAV virions is between 7.5 and 8.0.

47. Elevidys® is a pharmaceutical composition of purified rAAV virons, comprising a "serotype rh74 (AAVrh74) based vector containing the ELEVIDYS micro-dystrophin transgene under the control of the MHCK7 promoter." Exhibit C, § 11. On information and belief, Elevidys® is manufactured using a chromatography-based purification method. Exhibit G, § 3.2.P.2.3 Manufacturing Process Development ("Process B clinical DP is manufactured at Catalent BioPark and has been validated as the intended commercial process. . . ."); *id.,* § 10.A EXECUTIVE SUMMARY ("Process B utilizes a scaled-up purification method that incorporates chromatography-based methods purification of the DP, including separation of the empty capsid residuals from the full capsids.").

48. On information and belief, Elevidys® is manufactured to prevent aggregation of the rAAV virions within the drug product. *See* Exhibit G, § 3.2.P.3.2 Batch Formula (Defendants represented to the FDA that the drug product "[v]ials found to have defects, including visible particles are removed."); *id.*, § 3.2.P.5. Control of Drug Product (The Elevidys® drug product release specifications require the analytical testing of certain attributes of the final drug product before it is permitted to enter the market, including the testing of "Particulate Matter." The FDA reviewer commented that this attribute had "[a]cceptable compendial limits."); *id.*, § 3.2.P.2.6 Compatibility ("According to the Applicant, low levels of visible particles were

observed in SRP-9001 drug product vials during the 100% visual inspection process in some batches and were rejected."). On information and belief, the FDA would not approve the product if it failed to meet this requirement.

49. On information and belief, Elevidys® is manufactured recombinantly using a cell bank, and the drug substance is purified by first providing a lysate containing the rAAV virions. Exhibit G § 3.2.A.2 Adventitious Agents Safety Evaluation ("generation of cell banks and DS manufacturing" were reviewed in "3.2.S.2.3 Control of Materials. The materials are satisfactorily controlled.").

50. On information and belief, the rAAV virions in Elevidys® are purified from the lysate using chromatography. Exhibit G, § 3.2.P.2.3 Manufacturing Process Development ("Process B clinical DP is manufactured at Catalent BioPark and has been validated as the intended commercial process . . . ."); *id.,* § 10.A EXECUTIVE SUMMARY ("Process B utilizes a scaled-up purification method that incorporates chromatography-based methods purification of the DP, including separation of the empty capsid residuals from the full capsids.").

51. Elevidys® is prepared by adding to the purified virions the salt of a multivalent ion, magnesium chloride, selected from the claimed group to produce a preparation of virions with an ionic strength of at least 200 mM. Exhibit C, § 11 Description ("Each vial [of Elevidys®] contains an extractable volume of 10 mL and the following excipients: 200 mM sodium chloride, 13 mM tromethamine HCl, 7 mM tromethamine, 1 mM magnesium chloride, 0.001% poloxamer 188.").

52. Elevidys® has a "nominal concentration of 1.33 x 10^{13} vg/mL," which is within the claimed range of 1×10^{13} vg/ml up to 6.4×10^{13} vg/ml. Exhibit C, § 11 Description.

53. The pH of the purified preparation of rAAV virions of Elevidys® is between 7.5 and 8.0. The pH of Elevidys® can be calculated from its components, and is between 7.5 and 8.0. Exhibit C, § 11 Description ("Each vial [of Elevidys®] contains an extractable volume of 10 mL and the following excipients: 200 mM sodium chloride, 13 mM tromethamine HCl, 7 mM tromethamine, 1 mM magnesium chloride, 0.001% poloxamer 188.").

54. Claim 7 depends from claim 1 and recites:

> The method of claim 1, wherein, after addition of the one or more salts of multivalent ions, recovery of the virions is at least about 90% following filtration of the preparation of virions through a 0.22 µm filter.

55. On information and belief, the recovery of the purified, AAV virions of Elevidys® is at least about 90% recovered following filtration of the Elevidys® composition through a 0.22 µm filter, after the addition of a salt of a multivalent ion, magnesium chloride. The manufacturing process for Elevidys® includes sterile filtration. Exhibit G, § 10.A. EXECUTIVE SUMMARY at p. iv. On information and belief, the sterile filtration is 0.22 µm filter. *See also* Exhibit C, § 2.4 Administration ("Recommended supplies and materials: Syringe infusion pump, 0.2 micron PES* in-line filter, PVC* (non-DEHP*), polyurethan IV infusion tubing and catheter); Exhibit G, § 3.2.P.2.6 Compatibility ("A study to assess the in-use compatibility and effectiveness of a 0.2 µm in-line filter as part of DP administration to remove potential intrinsic particulates in the [drug product], was conducted."). On information and belief, the yield of Elevidys® following sterile filtration would be within plus or minus 10% of the FDA approved drug product specification (i.e., at least 90%).

56. Defendants' practice of the patented methods claimed in the '721 Patent prior to the expiration of the '721 Patent constitutes direct infringement under 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, of at least claims 1 and 7 of the '721 Patent.

57. Defendants jointly infringe the '721 Patent by contracting with Catalent to manufacture Elevidys® under the direction and under the control of Sarepta, and/or by forming a joint enterprise with manufacturers including Catalent for the manufacture of Elevidys®. *See, e.g.*, Sarepta May 2024 10-Q at p. 22 ("We have adopted a hybrid development and manufacturing strategy in which we have built internal expertise relative to all aspects of AAV-based manufacturing . . . while closely partnering with experienced manufacturing partners to expedite development and commercialization of our gene therapy programs. We have secured manufacturing capacity at Thermo and Catalent to support our clinical and commercial manufacturing demand for ELEVIDYS and our LGMD programs."); Exhibit H, Catalent Jan. 5, 2023 Press Release at pp. 1-2 ("Catalent will be Sarepta's primary commercial manufacturing partner for this therapy [Elevidys®]."); Exhibit F, § 3.2.A Facilities Table (The Elevidys® drug substance and drug product are manufactured in Catalent facilities in Harmans, MD and Baltimore, MD, respectively). On information and belief, Defendants condition receipt of contractual benefits upon performance by Catalent of the steps of the patented methods of the '721 Patent in the manufacture of Elevidys®, and establish the manner and timing of Catalent's performance.

58. Defendants have infringed the '721 Patent by selling and offering to sell Elevidys®, made by the methods claimed in the '721 Patent to third parties. *See, e.g.*, Exhibit D, June 22, 2023, Accelerated BLA Approval Letter at p. 1 (issuing "U.S. License No. 2308 to Sarepta Therapeutics, Inc." which "authorizes you to introduce or deliver for introduction into interstate commerce" Elevidys®.); Sarepta 2024 Form 10-K at p. 8 ("We launched ELEVIDYS in the second quarter of 2023."); *id.* at p. 76 (Sarepta recorded more than $200 million in revenue from U.S. sales of Elevidys® in 2023 alone.)

59. On information and belief, at least as of the date of the complaint, Defendants have actively induced Catalent to infringe one or more claims of the '721 Patent, including but not limited to claims 1 and 7, under 35 U.S.C. § 271(b), by instructing and contracting with Catalent to manufacture Elevidys® in accordance with the claimed methods, with knowledge of the '721 Patent and that the induced acts would constitute infringement.

60. Moreover, on information and belief, Defendants contribute to infringement of the '721 Patent, including but not limited to claims 1 and 7, under 35 U.S.C. § 271(c) by supplying materials or apparatuses for use in practicing the patented method, such as the provision of engineered rAAV virions to manufacture the finished drug product, such materials or apparatuses having no substantially non-infringing uses, with knowledge of the '721 Patent and its infringement at least as of the date of the complaint.

61. Plaintiff has suffered damages, including pre-suit damages, as a result of Defendants' infringement of the '721 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

A. Enter judgment that Defendants have infringed the '542 Patent and the '721 Patent;

B. Enter judgment that Defendants' infringement of the '542 Patent and the '721 Patent is deliberate and willful at least as of the date of the filing of the complaint;

C. Award damages adequate to compensate Plaintiff for Defendants' infringement, including increased damages up to three times the amount found or assessed, together with pre-judgment and post-judgment interest and costs, under 35 U.S.C. § 284;

D. Enter judgment that this case is exceptional and award Plaintiff its reasonable attorneys' fees, costs, and expenses, under 35 U.S.C. § 285; and

E. Award such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues so triable.

Dated: July 26, 2024

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