

**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.

C.A. No. 23-667-RGA

**PLAINTIFFS' INITIAL CLAIM CHART RELATING ACCUSED PRODUCT TO THE
ASSERTED CLAIMS OF U.S. PATENT 11,680,274**

Plaintiffs The Trustees of the University of Pennsylvania (“University”) and REGENXBIO, Inc. (“REGENXBIO,” together with University, “Plaintiffs”) pursuant to the Court’s September 19, 2023 Scheduling Order (D.I. 20) and Paragraph 4(c) of the Default Standard for Discovery, set forth herein their initial claim chart relating to infringement by Defendants Sarepta Therapeutics, Inc., Sarepta Therapeutics Three, LLC (together “Sarepta”), and Catalent Inc. (“Catalent,” together with Sarepta, “Defendants”) of the asserted claims of United States Patent No. 11,680,274 (“the ’274 patent”).

Accused Products

Based on the information currently available to Plaintiffs, Plaintiffs identify the following Accused Product: the gene therapy product Defendants refer to as “SRP-9001 (AAVrh74.MHCK.micro-dystrophin)” and which Sarepta markets and sells under the name

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“ELEVIDYS.” SRP-9001 (AAVrh74.MHCK.micro-dystrophin) / ELEVIDYS is referred to herein as the “Accused Product.”

Plaintiffs reserve the right to amend this identification to include additional products as discovery proceeds and/or, for example, should Sarepta bring any additional recombinant adeno-associated virus (“AAV”) gene therapy product or products to market.

The Accused Product meets the limitations of the Asserted Claims as identified and explained below. Plaintiffs therefore accuse the Accused Product of infringing the Asserted Claims of the '274 patent. Plaintiffs’ claim chart, attached hereto as Exhibit 1, sets forth Plaintiffs’ allegations of infringement against the Accused Product.

Asserted Claims

Based on the information currently available to Plaintiffs, Plaintiffs assert that the Accused Product infringes the following claims of the patent-in-suit (the “Asserted Claims”):

Patent No.	Asserted Claims
11,680,274	1, 3-6, 8

Discovery in this case is ongoing, and Plaintiffs’ investigation is ongoing. For any claims not listed in the table above at this time, Plaintiffs reserve all rights to assert any presently unasserted claims pending further investigation and discovery.

Direct Infringement Under Section 271(a)

By importing, making, using, offering to sell, and/or selling the Accused Product, Defendants are liable for direct infringement of the Asserted Claims of the patent-in-suit under 35 U.S.C. § 271(a). Defendants actively, knowingly, and intentionally directly infringe, and will continue to infringe, the Asserted Claims, either literally and/or under the doctrine of equivalents, by importing, making, using, offering to sell, and/or selling the Accused Product.

[REDACTED]

As explained in more detail in the accompanying claim chart, the Accused Product is a recombinant AAV that contains an AAV capsid comprising AAV vp1, vp2, and vp3 proteins. Specifically, the Accused Product's AAV vp1 protein has an amino acid sequence that is at least 95% identical to the full length of amino acids 1 to 738 of SEQ ID NO:4 in the '274 patent, and the amino acid residue corresponding to position [REDACTED] in SEQ ID NO:4 is [REDACTED] when aligned along the full length of amino acids 1 to 738 of SEQ ID NO: 4. Sarepta's core technical documents only provide the nucleic acid sequence of the AAV vp1 protein, not the amino acid sequence. (*See, e.g.,* SRPT274-0001437-0001446; SRPT274-0002043-0002062 at SRPT274-0002053-0002012.) Sarepta's core technical documents state that the AAV capsid protein is encoded by the nucleic acid sequence found at positions [REDACTED], which are identical in Sarepta's [REDACTED]-[REDACTED] plasmids. (SRPT274-0002043-0002062 at SRPT274-0002046, SRPT274-0002048, SRPT274-0002053-SRPT274-00061.) Plaintiffs utilized the nucleic acid sequence at those positions to determine the corresponding amino acid sequence with a web-based translation tool, <https://web.expasy.org/translate/>. (*See* Appendix A.) The amino acid sequence derived from Sarepta's nucleic acid sequence is identical to the amino acid sequence published for the rh74 capsid protein in U.S. Patent No. 9,434,928.

The nucleic acid sequences provided by Sarepta and the amino acid sequence that Plaintiffs generated by translating that nucleic acid sequence were then compared to the sequences required by the Asserted Claims using an online tool, Clustal O, <https://www.ebi.ac.uk/Tools/msa/clustalo/>. The results of that sequence alignment and the resulting percent identity to the sequence required by the Asserted Claims is shown in Appendix B.

Product, but perform certain activities with respect to the Accused Product outside the United States, Plaintiffs reserve the right to assert infringement under 35 U.S.C. § 271(f).

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