

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

GENZYME CORPORATION)	
)	
Plaintiff,)	C.A. No. 24-0882 (RGA)
)	
v.)	JURY TRIAL DEMANDED
)	
SAREPTA THERAPEUTICS, INC. and SAREPTA THERAPEUTICS THREE, LLC,)	[REDACTED]
)	[REDACTED]
Defendants.)	[REDACTED]
)	
)	
)	

**PLAINTIFF’S SUPPLEMENTAL INITIAL CLAIM CHARTS ON INFRINGEMENT
PURSUANT TO PARAGRAPH 4(C) OF THE DEFAULT STANDARD FOR
DISCOVERY**

Pursuant to Paragraph 4(c) of the Default Standard for Discovery, Including Discovery of Electronically Stored Information and the parties’ May 29, 2025 stipulation to amend the Scheduling Order in this case (D.I. 78), Plaintiff Genzyme Corporation (collectively, “Genzyme” or “Plaintiff”) provides these Supplemental Initial Claim Charts on Infringement by Defendants Sarepta Therapeutics, Inc. and Sarepta Therapeutics Three, LLC (collectively, “Sarepta” or “Defendants”) of U.S. Patent Nos. 12,031,894 (the “’894 patent”), 12,013,326 (the “’326 patent”), 11,698,377 (the “’377 patent”), 12,123,880 (the “’880 patent”), 12,298,313 (the “’313 patent”) (collectively, the “Additional Patents”) by Sarepta’s Elevidys® (delandistrogene moxeparvovec-rokl) gene therapy product.

Disclosures Under Paragraph 4(c) of the Default Standard for Discovery

Sarepta’s Elevidys® product (BLA No. 125781) (delandistrogene moxeparvovec-rokl) is a onetime recombinant adeno-associated virus (“rAAV”) gene therapy intended to treat

individuals at least four years of age with Duchenne Muscular Dystrophy (“DMD”). Elevidys[®] is an adeno-associated virus-based gene therapy product that delivers a copy of a human micro-dystrophin transgene into target muscle tissues, resulting in the expression micro-dystrophin protein, thus treating DMD.

In addition to claims 1, 6, and 7 of the ’721 patent and claims 3, 5, and 6 of the ’542 patent as asserted in Genzyme’s April 16, 2025 Initial Claim Charts with respect to those patents, Sarepta’s commercial manufacture, importation, use, offer to sell, or sale of Elevidys[®] infringes, either literally or under the doctrine of equivalents, at least claims 1-5, 10-23, and 30 of the ’894 patent; claims 1-3, 7-9, 12-16, 20-22, 25-27, 30 of the ’326 patent; claims 1-8, 11, 13-17, and 20 of the ’377 patent; claims 1-5, 7, 10-15, and 21 of the ’880 patent; and claims 1-6 and 11-27 of the ’313 patent (collectively, the “Asserted Claims”) under 35 U.S.C. § 271(a).

To the extent that Sarepta outsources to or contracts with any other third-parties for the manufacture, development, testing, and/or quality control of Elevidys[®], Sarepta infringes, literally or under the doctrine of equivalents, the Asserted Claims under 35 U.S.C. § 271(b).

To the extent that Sarepta supplies materials or apparatuses for use in practicing the patented methods of the Asserted Claims, such as the provision of engineered rAAV virions to manufacture the finished Elevidys[®] drug product, such materials or apparatuses having no substantially non-infringing uses, with knowledge of the Asserted Claims, Sarepta infringes, literally or under the doctrine of equivalents, the Asserted Claims under 35 U.S.C. § 271(c).

With respect to the Additional Patents, Sarepta has admitted to having knowledge of the ’894 patent at least as of July 26, 2024; knowledge of the ’326 patent at least as of July 26, 2024; knowledge of the ’377 patent at least as of July 26, 2024; knowledge of the ’880 patent at least as of October 31, 2024; and knowledge of the ’313 patent at least as of May 13, 2025; and Sarepta

is willfully infringing the Asserted Claims.

Further details on how Sarepta's manufacture of Elevidys[®] infringes or will infringe each of the Asserted Claims of the '894 patent, the '326 patent, the '377 patent, the '880 patent, and the '313 patent are provided in the Supplemental Initial Claim Charts attached as Exhibits C-G. Any allegation in Genzyme's contentions that Sarepta performs a method step means that Sarepta performs, directs, or induces others to perform such a method step, such that Sarepta is liable for direct or indirect infringement of each Asserted Claim, either literally or under the doctrine of equivalents. During development of Elevidys[®], Sarepta has likely generated numerous versions of the documents referenced in Genzyme's Supplemental Initial Claim Charts. Any citation to such documents is intended to be exemplary of Sarepta's infringement and is not exhaustive. Because additional discovery is ongoing at this time, Genzyme provides these Supplemental Initial Claim Charts based on information presently known to Genzyme.

Accordingly, Genzyme reserves the right to further supplement and/or amend the Asserted Claims and its Initial Claim Charts based on additional information discovered during this litigation, including documents produced by Sarepta during this litigation. In particular, Genzyme reserves the right to rely on fact deposition testimony and exhibits entered in such depositions in support of its contentions that Sarepta's Elevidys[®] (delandistrogene moxeparvovec-rokl) gene therapy product and methods related thereto infringe or will infringe each of the Asserted Claims, and to supplement and/or amend these disclosures in view of such discovery. In particular, to date, Sarepta has failed to produce discovery into technical documents outside of its BLA, including specific technical documents cited in Sarepta's BLA, that are highly relevant to infringement of the Asserted Claims. As such, Genzyme's infringement contentions are preliminary, and Genzyme reserves the right to supplement its

contentions upon discovery of additional documents, whether by agreement of the parties or by court order.

Genzyme further reserves the right to supplement and/or amend these contentions based on expert discovery in this case. Genzyme will submit expert reports in accordance with the scheduling order regarding Sarepta's infringement of the Asserted Claims. Such expert disclosures may include further evidence of Sarepta's infringement. Genzyme incorporates its forthcoming expert reports as if fully set forth herein.

In addition, the Court has not yet entered a claim construction order in this case. Genzyme further reserves the right to supplement and/or amend these contentions based on a claim construction order entered by the Court, if necessary. Genzyme further reserves the right to supplement and/or amend these contentions based on any testing that may be performed.

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REDACTED