

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

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

C.A. No: 21-1015-JLH

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD. and NS
PHARMA, INC.,

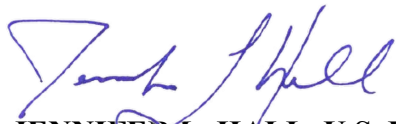
Plaintiff/Counter-Defendants.

MEMORANDUM OPINION

Amanda S. Williamson, Christopher J. Betti, Krista V. Venegas, Wan-Shon Lo, Maria Doukas, Zachary Miller, Guylaine Haché, Michael T. Sikora, MORGAN, LEWIS & BOCKIUS LLP, Chicago, Illinois. Amy M. Dudash, MORGAN, LEWIS & BOCKIUS LLP, Wilmington, Delaware. Attorneys for Nippon Shinyaku Co., Ltd. And NS Pharma, Inc.

Charles E. Lipsey, J. Derek McCorquindale, Ryan P. O'Quinn, L. Scott Burwell, FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP, Reston, Virginia. Jack B. Blumenfeld, Megan E. Dellinger, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware. Attorneys for Sarepta Therapeutics, Inc. and the University of Western Australia.

May 1, 2024
Wilmington, Delaware



JENNIFER L. HALL, U.S. DISTRICT JUDGE

Having reviewed the briefing on Sarepta Therapeutics, Inc. and the University of Western Australia's (together, "Sarepta's") Motion for Summary Judgment of Infringement of U.S. Patent Nos. 9,994,851 ("851 patent") and 10,277,590 ("590 patent") (Motion #1) (D.I. 396, 409, 411, 460, 461, 490, 491), the motion will be GRANTED, for the following reasons:

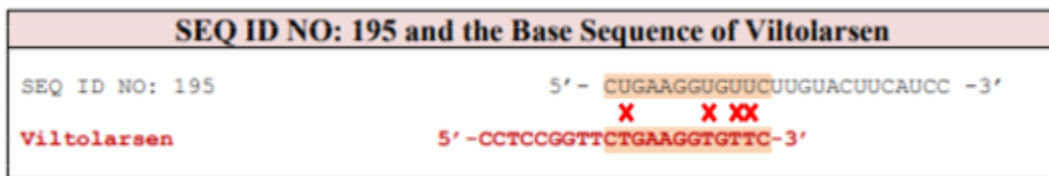
1. Sarepta claims that Nippon Shinyaku Co., Ltd., and NS Pharma, Inc. (together, "NS") infringe claims 1 and 2 of the '851 patent and claims 1 and 2 of the '590 patent. Each of the claims requires "[a]n antisense oligonucleotide . . . comprising a base sequence . . . wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID No: 195), in which uracil bases are thymine bases . . ." '851 patent, claims 1-2; '590 patent, claims 1-2.

2. Before this case was reassigned to me, the parties participated in *Markman* proceedings before the Honorable Gregory B. Williams. In its *Markman* briefing, NS argued that the asserted claims were indefinite because a person of ordinary skill in the art would not be able to tell whether the phrase "in which uracil bases are thymine bases" modifies only the limitation "at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID No: 195)," or whether the phrase "in which uracil bases are thymine bases" requires that the entire antisense oligonucleotide must have thymine bases instead of uracil bases.¹ (D.I. 173 at 48.) Sarepta argued that the phrase "in which uracil bases are thymine bases" refers to the entire

¹ Nowhere in NS's *Markman* briefing did it suggest that the claims *both* require "[a]n antisense oligonucleotide . . . comprising a base sequence . . . wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C" where the uracil bases are uracil bases (not thymine bases), *and* require that the entire claimed antisense oligonucleotide have thymine bases instead of uracil bases. As explained below, everyone agrees that such a construction would make infringement impossible.

antisense oligonucleotide. (D.I. 173 at 42.) In other words, Sarepta argued that the claim requires an antisense oligonucleotide with “at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID No: 195)” where the uracil bases (*i.e.*, “U”) are replaced with thymine bases (*i.e.*, “T”)—meaning that the antisense oligonucleotide must have at least 12 consecutive bases of CTG AAG GTG TTC TTG TAC TTC ATC C—and that the rest of the antisense oligonucleotide also has thymine bases instead of uracil bases. Judge Williams issued a claim construction opinion in which he concluded that the phrase “in which uracil bases are thymine bases” was not indefinite and that “a person of ordinary skill in the art would be clearly informed, with reasonable certainty, that the [phrase] refers to the entire antisense oligonucleotide.” (D.I. 248 at 28; D.I 249.)

3. Sarepta now seeks summary judgment that NS’s viltolarsen product infringes claims 1 and 2 of the ’851 patent and claims 1 and 2 of the ’590 patent. NS responds that its product does not satisfy the phrase “wherein the base sequence comprises at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C (SEQ ID No: 195)” because its product has a sequence containing thymine bases instead of uracil bases:



(D.I. 460 at 3 (NS Answering Brief).) In other words, NS’s argument is that its product does not infringe because the asserted claims cannot be infringed—it is “impossible” for a product to both (i) contain 12 consecutive bases from SEQ ID NO: 195, which has uracil bases, and (ii) contain thymine bases instead of uracil bases. (D.I. 460 at 10; *see also id.* at 8–9 (“Since every set of 12

consecutive bases of SEQ ID NO: 195 includes at least one uracil base, it is impossible for an antisense oligonucleotide to simultaneously meet both limitations.”.)

4. NS’s non-infringement position is premised on a new claim construction argument, and the Court rejects it. Even if the Court were inclined to revisit Judge Williams’s claim construction (and it is not), the claims do not require “at least 12 consecutive bases of CUG AAG GUG UUC UUG UAC UUC AUC C” where the uracil bases are uracil bases. Rather, the claims expressly require that the “uracil bases are thymine bases.”

5. There is no genuine dispute of fact that NS’s viltolarsen product includes 12 consecutive bases of SEQ ID NO: 195 “in which uracil bases are thymine bases.” (D.I. 411 at ¶¶ 1.21–1.24; D.I. 466 at ¶¶ 1.21–1.24). NS points to no other dispute of material fact that would preclude summary judgment on the issue of infringement.² Summary judgment on the issue of infringement of claims 1 and 2 of the ’851 patent and claims 1 and 2 of the ’590 Patent will be GRANTED.

² Indeed, during the April 18, 2024 teleconference, counsel for NS represented that Sarepta’s motion essentially came down to a claim construction dispute and that, if decided against NS, it would stipulate to infringement. (See April 18, 2024 Teleconference Tr. 24:17–19 (“Again, if you do decide that in favor of Sarepta, we will stipulate to infringement obviously. And that relates to one claim construction dispute.”).)

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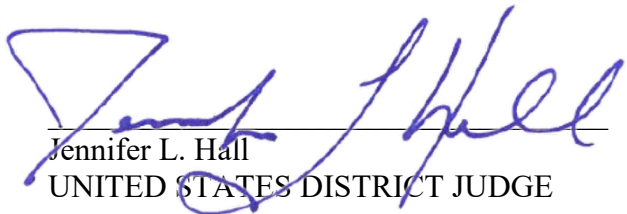
NIPPON SHINYAKU CO., LTD. and NS
PHARMA, INC.,

Plaintiff/Counter-Defendants.

ORDER

This 1st day of May, 2024, consistent with the Memorandum Opinion issued this same day, **IT IS ORDERED** that

Sarepta Therapeutics, Inc. and the University of Western Australia's Motion for Summary Judgment of Infringement of U.S. Patent Nos. 9,994,851 and 10,277,590 (Motion #1) (D.I. 396) is GRANTED.



Jennifer L. Hall
UNITED STATES DISTRICT JUDGE