**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

| | |
|---|---|
| **Charles Seife**<br><br>***Plaintiff*,**<br><br>**v.**<br><br>**Food and Drug Administration and Department of Health and Human Services**<br><br>***Defendants***<br>**and**<br><br>**Sarepta Therapeutics, Inc.**<br><br>***Defendant-Intervenor*.** | **Case No. 1:17-cv-3960 (JMF)** |

**MEMORANDUM OF SAREPTA THERAPEUTICS, INC.**
**IN OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE**

ARNOLD & PORTER KAYE SCHOLER LLP
Daniel Bernstein
250 West 55th Street
New York, NY 10019
(212) 836-8000
daniel.bernstein@arnoldporter.com

Kristen E. Ittig
Stuart W. Turner
Amanda J. Sherwood
601 Massachusetts Avenue, N.W.
Washington, DC 20001
(202) 942-5000
kristen.ittig@arnoldporter.com
stuart.turner@arnoldporter.com
amanda.sherwood@arnoldporter.com

*Attorneys for Defendant-Intervenor*
*Sarepta Therapeutics, Inc.*

**ORAL ARGUMENT REQUESTED**

# TABLE OF CONTENTS

## TABLE OF AUTHORITIES

**Page(s)**

**Cases**

**Statutes**



**Other Authorities**

Defendant-Intervenor Sarepta Therapeutics, Inc. ("Sarepta") respectfully submits this memorandum of law in opposition to Plaintiff's Motion to Strike.

## INTRODUCTION

Plaintiff's motion to strike the Declaration of Ian Estepan in support of Sarepta's motion for summary judgment is unnecessary and unfounded. Whatever issues Plaintiff may have with the declaration can be addressed through the pending motions for summary judgment. As explained below and in Sarepta's opposition to Plaintiff's motion for summary judgment, Mr. Estepan's declaration is more than sufficient to carry Sarepta's burden of showing that summary judgment should be entered in its favor. The declaration describes Mr. Estepan's position at Sarepta, industry experience, and review of relevant documents, all of which establish his personal knowledge.

Moreover, the declaration explains in detail why disclosure of the information withheld pursuant to Freedom of Information Act ("FOIA") Exemption 4 is likely to cause Sarepta substantial competitive harm. The FOIA Exemption 4 case law does not require the type of expert economic analysis that might be expected in an antitrust case. Nor does the FOIA Exemption 4 case law require the level of specificity that Plaintiff demands from Sarepta. While Plaintiff may disagree with Mr. Estepan's conclusions, there is simply no basis for striking his declaration. And for the avoidance of any doubt, Mr. Estepan has submitted a second declaration in opposition to this motion, laying out in even greater detail the basis for his personal knowledge and opinion that the relief Plaintiff seeks would cause Sarepta substantial competitive harm.

## ARGUMENT

### I. THE MOTION TO STRIKE IS UNNECESSARY

Plaintiff's motion to strike needlessly multiplies the number of briefs in this case, burdening Defendants and the Court. Rather than file a motion to strike, Plaintiff simply could have noted his objections in his opposition to Defendants' motion for summary judgment. *See* Fed. R. Civ. P. 56(c)(2). "There is no need to make a separate motion to strike." *Id.*, Advisory Committee Note of 2010. As a court in this district stated in a decision cited by Plaintiff, any portions of a declaration that do not conform to Rule 56 simply may be disregarded. *Rus, Inc. v. Bay Industries, Inc.*, 322 F. Supp. 2d 302, 307 (S.D.N.Y. 2003).

Indeed, courts in the Second Circuit strongly disfavor the use of motions to strike to challenge materials submitted in support of or in opposition to a motion for summary judgment. As explained in *Martin v. Town of Westport*:

> The Federal Rules of Civil Procedure do not explicitly allow motions to strike for such a purpose. Rule 12(f) reads that, upon a motion or the court's own initiative, 'the court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.' Fed. R.Civ.P. 12(f). Affidavits and Local Rule 56(a) Statements are not 'pleadings' under the Federal Rules. See Fed.R.Civ.P. 7(a). Moreover, Rule 56, which governs summary judgment, does not provide a 'motion to strike' as a tool in the summary judgment process. See Fed.R.Civ.P. 56.

558 F. Supp. 2d 228, 230 (D. Conn. 2008). The *Martin* court and others thus have concluded that "in the context of summary judgment, motions to strike 'are unnecessary and produce only redundant statements by the court that it has not relied on such inadmissible evidence in deciding the summary judgment motion.'" *Id.* (quoting *Ricci v. Destefano*, No. 3:04 CV 1109 JBA, 2006

WL 2666081 (D. Conn. Sept.15, 2006)). "If a party wishes to argue that an asserted material fact is not supported by the evidence, that party may do so in its summary judgment briefing." *Id.*[1]

Other courts agree that motions to strike are inappropriate in the context of a summary judgment motions. *See, e.g.*, *Hagen v. Siouxland Obstetrics & Gynecology, P.C.*, 934 F. Supp. 2d 1026, 1042-43 (N.D. Iowa 2013) (denying motion to strike because such a motion is to be used to strike matter from pleadings, not to strike materials submitted in opposition to summary judgment); *Mobile Shelter Sys. USA, Inc. v. Grate Pallet Solutions, LLC*, 845 F. Supp. 2d 1241, 1253 (M.D. Fla. 2012) (denying motion to strike on grounds that it is an improper device to circumvent page limits on a motion for summary judgment and that the proper method to object to evidence submitted on summary judgment is for party opposing motion to object to movant's affidavits through material submitted in opposition to motion). *Accord* Moore's Federal Practice § 56.91[4] ("Motions to Strike Are Neither Necessary Nor Wanted by the Court").

For this reason alone, Plaintiff's motion to strike should be denied.

## II. MR. ESTEPAN HAS PERSONAL KNOWLEDGE OF THE MATTERS ABOUT WHICH HE TESTIFIES

Plaintiff's motion to strike also should be denied because the Estepan Declaration complies with the requirements of Rule 56. Contrary to Plaintiff's assertion, Mr. Estepan's declaration is based on personal knowledge.

As the case law cited by Plaintiff makes clear, "[a]n affiant's conclusions based on personal observations over time … may constitute personal knowledge, and an affiant may testify as to the contents of records she reviewed in her official capacity." *Searles v. First Fortis*

[1] Even in the context of a motion pursuant to Rule 12(f), courts in the Second Circuit have held that motions to strike are generally disfavored. *See Coach, Inc. v. Kmart Corp.*, 756 F. Supp. 2d 421, 425 (S.D.N.Y. 2010); *Illiano v. Mineola Union Free Sch. Dist.*, 585 F. Supp. 2d 341, 357 (E.D.N.Y. 2008).

*Life Ins. Co.*, 98 F. Supp. 2d 456, 461 (S.D.N.Y. 2000). "The test for admissibility is whether a reasonable trier of fact could believe the witness had personal knowledge." *Id.* Applying this test, the *Searles* court found that the affiant's position with the company "qualified her to review the relevant business materials in an official capacity and make sworn statements based upon those materials," and that she therefore had "personal knowledge of the facts about which she testified." *Id.* Other courts similarly have inferred personal knowledge from a witness's position with a company. *See, e.g. DIRECTV, Inc. v. Budden*, 420 F.3d 521, 529-30 (5th Cir. 2005) (collecting cases for the proposition that there are no "magic words" necessary to demonstrate personal knowledge and finding that an affidavit was not deficient for failure to state that it was based on personal knowledge when personal knowledge was reasonably inferred from the affiant's position with the plaintiff corporation).

Here, personal knowledge can easily be inferred from Mr. Estepan's position with Sarepta. Mr. Estepan stated that he is "the Chief of Staff and Head of Corporate Affairs, overseeing Investor Relations, Corporate Communications, and Program Management." (Estepan Decl. ¶ 1.) The case law that Plaintiff claims to illuminate the meaning of "investor relations" is wholly irrelevant. (*See* Pl.'s Mot. to Strike at 4.) Those cases describe the positions of different individuals with different titles at different companies; they, of course, say nothing about Mr. Estepan's role and responsibilities at Sarepta or the basis of his personal knowledge in this matter. Moreover, those cases have nothing to do with FOIA Exemption 4 and thus fail to rebut the natural inference that a company's investor relations professional has personal knowledge about the company's business and the competition it faces. In any event, as Mr. Estepan himself explains, his job is not limited to Investor Relations or public relations. He is also responsible for program management, including the execution of corporate strategic

initiatives with the goal of expediting the advancement of clinical compounds through the regulatory process." (*Id.* ¶ 2.) In this capacity, Mr. Estepan "closely track[s] the rapidly evolving competitive landscape in Duchenne muscular dystrophy." (*Id.*)

Further establishing a basis for Mr. Estepan's personal knowledge is the industry experience he describes. He has "16 years of experience in healthcare investing, specifically relating to the development of promising drug candidates, and over the past five years [he has] focused on speeding the clinical development of new therapies for patients with Duchene muscular dystrophy." (*Id.* ¶ 1.) Accordingly, Mr. Estepan is well-qualified to discuss the commercial and competitive landscape for DMD treatments, which is what is at issue here.

Mr. Estepan also refers to specific documents that inform his opinions. He refers to specific filings that Sarepta made to the FDA and other regulators (*see, e.g.*, *id.* ¶¶ 14, 20, 21, 36); specific FDA policies (*id.* ¶¶ 33, 38); and specific pages of the FDA's FOIA production to Plaintiff (*id.* ¶ 42). Lest there be any doubt, Mr. Estepan's declaration in opposition to this motion and to Plaintiff's motion for summary judgment makes explicit that he personally reviewed document productions made by the FDA to Plaintiff in this action, including redacted information. *See* Declaration of Ian Estepan dated July 30, 2018 ("Second Estepan Decl.") ¶ 25. This declaration also enumerates the types of documents he has reviewed and the people to whom he has spoken in forming his opinion about the likelihood of competitive harm from the disclosure of information withheld pursuant to FOIA Exemption 4. (*See, e.g.*, *id.* ¶¶ 6, 12-14, 16-24.)

Plaintiff offers no meaningful authority to support his motion to strike. The only FOIA decision Plaintiff cites that rejected testimony for lack of personal knowledge involved a witness who, unlike Mr. Estepan, admitted a lack of personal knowledge and offered only conjecture.

*See Nat'l Parks & Conservation Ass'n v. Kleppe*, 547 F. 2d 673, 683 (D.C. Cir. 1976). While the *National Parks* court rejected testimony from the witness who disclaimed personal knowledge, the court credited the testimony of another witness who, like Mr. Estepan, had "extensive knowledge and experience" in the relevant business, and, on that basis, the court affirmed withholdings under FOIA Exemption 4. *Id.* at 682-83.

Plaintiff's citation to *Teich v. FDA*, 751 F. Supp. 243 (D.D.C. 1990), is similarly misplaced. There, the court struck a corporate intervenor's declaration not for lack of personal knowledge (or for being conclusory or speculative); rather, the court "was forced to strike the declaration of Dow Corning's principal witness on basic fairness grounds" because Dow Corning had precluded the plaintiff's expert witnesses from testifying by enforcing protective orders obtained in product liability suits settled by Dow Corning. " *Id.* at 254. In other words, the *Teich* court's decision to strike a declaration was based on circumstances altogether absent from the present case.

## III. MR. ESTEPAN'S OPINIONS ARE WELL FOUNDED, AND EXPERT TESTIMONY IS NOT REQUIRED

Mr. Estepan does not purport to be, nor do the present motions for summary judgment require, an expert on genetics, DNA structure, exon skipping, FDA regulations, or economic analysis. Instead, Mr. Estepan offers facts, within his personal knowledge, about the company he works for, its research, its business, and its competitors—facts that inform his opinion on competitive harm, the relevant issue here. Federal Rule of Evidence 701 permits a lay witness such as Mr. Estepan to testify to an opinion "(a) rationally based on the witness's perception" and "(b) helpful to clearly understanding the witness's testimony or to determining a fact in issue." *See also Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 265 (2d Cir. 1995)

(finding that a company executive has "personal knowledge of his business … sufficient to make … [him] eligible under Rule 701 to testify as to how lost profits could be calculated").

In *National Parks v. Kleppe*, a case cited by Plaintiff, the D.C. Circuit refused to accept the contention that FOIA Exemption 4 case law requires a detailed economic analysis of the competitive environment, "the kinds of evidence more usually associated with elaborate antitrust proceedings…." 547 F.2d at 681. Nor was the D.C. Circuit "convinced of the feasibility and wisdom of imposing such a requirement in fourth exemption cases generally." *Id.* Indeed, the court noted that "a standard of proof that would render FOIA proceedings any more complex and time consuming would unnecessarily hinder the fair and expeditious administration or adjudication of FOIA requests." *Id.* at 681 n.24.

## IV. MR. ESTEPAN'S DECLARATION IS NOT CONCLUSORY OR SPECULATIVE

Plaintiff's attack on Mr. Estepan's declaration as conclusory and speculative is unavailing. Mr. Estepan explains at length why he believes that Sarepta is likely to suffer substantial competitive harm from disclosure. *See* Estepan Decl. ¶¶ 22-28 (discussing competitive harm resulting from disclosure of Sarepta's clinical study procedures), 29-33 (discussing competitive harm resulting from disclosure of Sarepta's clinical study results), 34-39 (discussing competitive harm resulting from disclosure of Sarepta's clinical study endpoints), 40-43 (discussing competitive harm resulting from disclosure of nonpublic adverse events), 44-60 (discussing competition in the marketplace).

The sole case Plaintiff cites to support the assertion that Mr. Estepan's declaration is conclusory as to the utility of the data to competitors is readily distinguishable. That case, *Major League Baseball Props. v. Salvino, Inc.*, 542 F. 3d 290 (2d Cir. 2008), concerned a battle of economic experts in an antitrust case; it had nothing to do with the sufficiency of a declaration in support of summary judgment in a FOIA case. In fact, it concerned precisely the type of

evidence that courts have found are unnecessary in adjudication of a FOIA Exemption 4 case. *See Nat'l Parks*, 547 F.2d at 681.

Plaintiff's critique of Mr. Estepan's declaration as improperly speculative also misses the mark. *National Parks v. Kleppe* makes clear that "[n]o actual adverse effect on competition need be shown." *Id.* at 683. All that needs to be shown is a *likelihood* of competitive harm. *Id.* For example, the Second Circuit has found information to be exempt under the competitive harm prong of Exemption 4 where "the *likely* commercial disadvantage resulting from release of the withheld information *could well* cause a reduction in the amount realizable for the receivership." *Nadler v. FDIC*, 92 F.3d 93, 97 (2d Cir. 1996) (emphasis added).

Cases from the D.C. Circuit further demonstrate that the specificity Plaintiff demands is not required. In *McDonnell Douglas Corp. v. U.S. Dept. of the Air Force*, a case cited in Plaintiff's summary judgment brief, the D.C. Circuit determined that, to satisfy the competitive harm test for FOIA Exemption 4, a party need not demonstrate how a competing firm would use the disclosed information "to model exactly or pinpoint precisely a rival's … strategy," because "pinpoint precision is not required to inflict substantial competitive harm." 375 F.3d 1182, 1193 (D.C. Cir. 2004). *See also Vaughn v. Rosen*, 484 F.2d 820, 826-27 (D.C. Cir. 1973) (finding that the analysis of the party opposing disclosure need not be so specific "that if made public would compromise the secret nature of the information"); *United Tech. Corp. v. U.S. Dept. of Defense*, 601 F.3d 557, 563 (D.C. Cir. 2010) ("In reviewing an agency's determination as to substantial competitive harm, we recognize that predictive judgments are not capable of exact proof, and we generally defer to the agency's predictive judgments as to the repercussions of disclosure." (internal citations omitted); *General Electric Co. v. Dept. of Air Force*, 648 F. Supp. 2d 95, 103

(D.D.C. 2009) (holding that a company "need not demonstrate precisely how the release of the information would cause competitive harm").

## V. MR. ESTEPAN HAS PROVIDED ADDITIONAL DETAILS ABOUT HIS PERSONAL KNOWLEDGE AND THE BASIS FOR HIS OPINIONS

For the avoidance of doubt, Mr. Estepan has submitted a declaration in opposition to Plaintiff's motion to strike (as well as in opposition to Plaintiff's motion for summary judgment). In that declaration, Mr. Estepan explains in greater detail the basis for his personal knowledge and his opinions. (*See* Second Estepan Decl. ¶¶ 4-26.) He describes the types of documents he has reviewed, people to whom he has spoken, facilities he has visited, and events he has attended. (*See id.*) He also expounds why, based on his many years of industry experience and position at Sarepta, he believes that release of the withheld information is likely to cause substantial competitive harm to the company, notwithstanding Plaintiff's arguments. (*See id.* ¶¶ 27-41.)

Defendants are well within their rights to submit a declaration in opposition to Plaintiff's motion to strike. *See* Fed. R. Civ. P. 6(c)(2) (contemplating an "opposing affidavit" in response to a motion); SDNY Local Rule 6.1(b) (same). Mr. Estepan's second declaration responds to Plaintiff's off-base criticisms of his first declaration; it does not offer any new opinions or contradict what was previously said. Given that Plaintiff has an opportunity to reply, there is no prejudice whatsoever to Plaintiff. Thus, assuming arguendo that there are any defects in Mr. Estepan's initial declaration (which there are not), his declaration in opposition to the motion to strike cures any such defects.

## CONCLUSION

For the reasons stated above and in Mr. Estepan's declarations, Plaintiff's motion to strike should be denied.

Dated: July 30, 2018

Respectfully Submitted,

*/s/ Daniel R. Bernstein*

Daniel R. Bernstein
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, New York 10019
(212) 836-8000
daniel.bernstein@arnoldporter.com

Kristen E. Ittig
Stuart W. Turner
Amanda J. Sherwood
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, DC 20001
(202) 942-5000
kristen.ittig@arnoldporter.com
stuart.turner@arnoldporter.com
amanda.sherwood@arnoldporter.com

*Attorneys for Defendant-Intervenor Sarepta Therapeutics, Inc.*