20-4072-cv
Seife v. FDA, et al.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term 2021

(Argued: March 7, 2022 Decided: August 5, 2022)

Docket No. 20-4072-cv

CHARLES SEIFE,

Plaintiff-Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellees,

-and-

SAREPTA THERAPEUTICS, INC.,

Intervenor-Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Before: CHIN, LOHIER, AND ROBINSON, *Circuit Judges*.

Appeal from a judgment of the United States District Court for the Southern District of New York (Furman, *J.*), entered October 6, 2020, in favor of two government agencies and a pharmaceutical company in this Freedom of Information Act ("FOIA") case. Plaintiff-appellant, a science writer and journalism professor, sought records from the government agencies relating to the pharmaceutical company's successful application for accelerated approval of a drug for the treatment of a neuromuscular disease. The agencies produced over 45,000 pages of documents, some of which were redacted under Exemption 4 of FOIA. The district court granted summary judgment for the agencies and the pharmaceutical company on the basis that the redacted information fell within Exemption 4 and publication would either cause foreseeable harm to the interests protected by Exemption 4 or was prohibited by law. Plaintiff-appellant appeals.

AFFIRMED.

JARED CARTER (Cortelyou C. Kenney, Tyler Valeska, *on the brief*), First Amendment Clinic, Cornell Law School, Ithaca, NY, *and* Thomas S. Leatherbury, Vinson & Elkins LLP, Dallas, TX, *and* David A. Schulz, Media Freedom & Information Access Clinic, Yale Law School, New Haven, CT, *for Plaintiff-Appellant.*

DOMINIKA TARCYNSKA, Assistant United States Attorney (Benjamin H. Torrance, Assistant United States Attorney, *on the brief*), *for* Audrey Strauss, United States Attorney for the Southern District of New York, New York, NY, *for Defendants-Appellees*.

KRISTEN E. ITTIG (Daniel R. Bernstein, Stuart W. Turner, Amanda J. Sherwood, and Aime Joo, *on the brief*), Arnold & Porter Kaye Scholer LLP, Washington, DC, *and* New York, NY, *for Intervenor-Defendant-Appellee.*

CHIN, *Circuit Judge*:

In this case, intervenor-defendant-appellee Sarepta Therapeutics, Inc. ("Sarepta") obtained accelerated approval from defendant-appellee the Food and Drug Administration (the "FDA") for a drug Sarepta created to treat a neuromuscular disease. During the approval process, which spanned some nine years, Sarepta submitted tens of thousands of pages of documents to the FDA, an agency within defendant-appellee Department of Health and Human Services ("HHS," and, together with Sarepta and the FDA, "Defendants").

Plaintiff-appellant Charles Seife, a science writer and journalism professor who has written about FDA practices, made a request to the FDA and

HHS under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, for documents submitted by Sarepta as part of the approval process. After the FDA constructively denied his request, Seife brought this action below.

During the course of the lawsuit, the FDA produced over 45,000 pages of records but redacted some pages pursuant to Exemption 4 of FOIA, which shields from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The district court held that the redactions were proper because the information fell within Exemption 4 and met the additional requirement set by the FOIA Improvement Act of 2016 (the "FIA"). Under the FIA, an agency shall withhold information under FOIA only if "the agency reasonably foresees that disclosure would harm an interest protected by an exemption" or if disclosure is "prohibited by law." 5 U.S.C. § 552(a)(8)(A). The principal issue presented on appeal is whether the district court correctly concluded that Defendants satisfied the foreseeable harm requirement. To answer that question, we must first discern the interests protected by Exemption 4.

We hold that the interests protected by Exemption 4 are the submitter's commercial or financial interests in information that is of a type held in confidence and not disclosed to any member of the public by the person to whom it belongs. Because Defendants have shown as a matter of law that the contested information falls within Exemption 4 and that disclosure would foreseeably harm Sarepta's commercial or financial interests, we AFFIRM the district court's grant of summary judgment for Defendants and denial of summary judgment for Seife.

BACKGROUND

A. *Statutory Framework*

Since 1967, FOIA has provided the public the right to request access to federal agency records or information. The statute reflects "a general philosophy of full agency disclosure unless information is exempted under clearly delineated statutory language." *Dep't of the Air Force v. Rose*, 425 U.S. 352, 360-61 (1976). Such statutory exemptions include, *inter alia*, Exemption 4, which provides that an agency need not disclose "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The agency has the burden of "justify[ing] the withholding

of any requested documents." *U.S. Dep't of State v. Ray*, 502 U.S. 164, 173 (1991). "All doubts are resolved in favor of disclosure." *Bloomberg, L.P. v. Bd. of Governors of the Fed. Reserve Sys.*, 601 F.3d 143, 147 (2d Cir. 2010) (quoting *Local 3, Int'l Bd. of Elec. Workers v. Nat'l Labor Rels. Bd.*, 845 F.2d 1177, 1180 (2d Cir. 1988)) (cleaned up).

In 2016, Congress enacted the FIA out of concern that "some agencies [were] overusing FOIA exemptions." S. Rep. No. 114-4 (2015), *as reprinted in* 2016 U.S.C.C.A.N. 321, 322. The FIA thus further limited agency withholding of requested documents. This reform codified executive branch policies adopting "a presumption in favor of disclosure [under FOIA]." Memorandum on the Freedom of Information Act, 74 Fed. Reg. 4683, 4683 (Jan. 21, 2009).[1]

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[1] When enacting the FIA, Congress explicitly referenced executive actions. A Senate Report explains that the FIA "codifies the policy established in January 2009 by President [Barack] Obama for releasing Government information under FOIA." S. Rep. No. 114-4 (2015), *as reprinted in* 2016 U.S.C.C.A.N. 321, 324. In January 2009, President Obama told all agencies to "adopt a presumption in favor of disclosure [under FOIA]." Memorandum on the Freedom of Information Act, 74 Fed. Reg. 4683, 4683 (Jan. 21, 2009). Subsequently, on March 19, 2009, the Department of Justice ("DOJ") issued a memorandum that referred to President Obama's memorandum and stated that DOJ would "defend a denial of a FOIA request only if (1) the agency reasonably foresees that disclosure would harm an interest protected by one of the statutory exemptions, or (2) disclosure is prohibited by law." Memorandum from Eric Holder, Attorney Gen., U.S. Dep't of Justice, to Heads of Exec. Dep'ts & Agencies at 2 (Mar. 19, 2009) (the "2009 DOJ Memorandum"). The language of the FIA mirrors that of the 2009 DOJ Memorandum.

In relevant part, the FIA amended FOIA to provide that, for FOIA requests submitted after June 30, 2016, an agency could withhold information only if it showed that the information both fell within an exemption of FOIA and at least one of two additional requirements was met. The requirements are that:

> (I) the agency reasonably foresees that disclosure would harm an interest protected by an exemption described in subsection (b); or
>
> (II) disclosure is prohibited by law.

5 U.S.C. § 552(a)(8)(A)(i)(I)-(II). Hence, the agency must show that disclosure of the requested information would foreseeably harm a protected interest or that disclosure is prohibited by law; otherwise, it must disclose the information, even if the information falls within one of the FOIA exemptions. Applicability of a FOIA exemption is still necessary -- but no longer sufficient -- for an agency to withhold the requested information. In essence, the FIA imposes an additional, independent burden on the agency.

Neither the Supreme Court nor this Court nor any of our sister circuits has had occasion to consider the burden imposed by the FIA in an Exemption 4 case.[2]

B. ***The Facts***

The relevant facts are drawn from the parties' affidavits and are undisputed.

On September 19, 2016, the FDA granted accelerated approval to Exondys 51, a drug developed by Sarepta to treat Duchenne muscular dystrophy ("DMD"). DMD is a fatal neuromuscular disease that affects young and adolescent males. In the United States, there are approximately 9,000 to 12,000 DMD patients.

Dystrophin is a protein, encoded by the dystrophin gene, that strengthens muscle fibers. DMD is caused by mutations in the dystrophin gene; the mutations result in a lack of dystrophin, which in turn results in loss of

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[2] The only FOIA exemption to receive appellate scrutiny post-FIA is Exemption 5. *See Machado Amadis v. United States Dep't of State*, 971 F.3d 364, 371 (D.C. Cir. 2020) (holding that the "chilling of candid advice [from attorneys within an agency] is exactly what [Exemption 5] seeks to prevent."); *cf. Nat. Res. Def. Council v. United States Env't Prot. Agency*, 19 F.4th 177, 194 n.18 (2d Cir. 2021) (referencing the district court's determination that "the EPA 'reasonably foresees that disclosure' of these records 'would harm an interest protected by' Exemption Five." (quoting 5 U.S.C. § 552(a)(8)(A)(i)(I)).

muscle tissue and function. Genes are composed of sequences known as exons. The most common type of DMD mutation deletes exons of the dystrophin gene -- that is, parts of the dystrophin gene -- thus misaligning the remaining parts of the gene and causing reduced dystrophin production.[3]

Exondys 51 was developed to target the dystrophin gene through a mechanism known as "exon-skipping." "Exon-skipping" causes the cellular machinery to skip the mutated part or parts of the dystrophin gene. With the mutated parts skipped, the remaining exons in the gene are read in the correct alignment, resulting in a shorter but functional form of the dystrophin gene. Sarepta began researching possible treatments for DMD beginning in the early 2000s and, after years of research, designed Exondys 51 -- also known as eteplirsen -- to skip exon 51 of the dystrophin gene. Around 13% of DMD mutations are amenable to exon 51 skipping, and an exon 51 mutation is the most common type of mutation amongst DMD patients.

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[3] In scientific terminology, the misalignment is caused by a "frame shift." J. App'x at 142. The exons -- the sequences in a gene -- are in a specific order and are read by ribonucleic acid ("RNA") to create proteins like dystrophin. When there is a "frame shift," exons are moved out of order and the RNA can no longer read the exons in the dystrophin gene to create dystrophin.

In 2007, Sarepta submitted the Exondys 51 Investigational New Drug application to the FDA. Sarepta then conducted Phase 1 proof-of-concept studies on the drug. As early as 2011, Sarepta moved to Phase 2 and conducted two Phase 2 studies, Study 201 and Study 202. Sarepta spent over three years developing the clinical study procedure for the studies, in part because of experimentation on dosing approaches and quantifying dystrophin. Both studies involved the same twelve DMD patients with mutations amenable to exon 51 skipping. Study 201 was placebo-controlled, double-blinded,[4] and conducted over twenty-eight weeks. Study 202, a long-term Phase 2b study, followed approximately six months after Study 201. In Study 202, all patients received Exondys 51.

The results of both studies were documented in clinical study reports. Each clinical study report was approximately 100 pages long and accompanied by thousands of pages of attachments with supporting data and background information. These clinical study reports and the study results were disseminated to only certain individuals within Sarepta; furthermore, Sarepta's

[4] In a double-blind clinical study, neither the patient nor the test-giver knows whether the patient is receiving the drug or the placebo. *See, e.g.*, Nat'l Inst. of Health, *Dictionary of Cancer Terms: Double-Blind Study*, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/double-blind-study (last visited August 5, 2022).

agreements with the clinical trial site included terms of confidentiality. In June 2015, Sarepta submitted the clinical study reports to the FDA as part of Sarepta's New Drug Application. The FDA received thousands of emails and calls from the public urging approval of Exondys 51.

On September 19, 2016, the FDA granted Exondys 51 accelerated approval, a special pathway for drugs treating serious conditions and providing a meaningful advantage over existing therapy. There was, however, intense internal conflict within the FDA over the approval of Exondys 51. Reviewers in the Division of Neurology Products, the Office of Biometrics, the Office of Clinical Pharmacology, the Office of Drug Evaluation-I, and the Office of New Drugs all assessed the documents Sarepta submitted in its application. These reviewers unanimously recommended that Exondys 51 not be approved due to deficiencies in Sarepta's clinical studies. The head of the Center for Drug Evaluation and Research, Dr. Janet Woodcock, nevertheless overrode the recommendation. One reviewer, the Director of the FDA's Office of Drug Evaluation-I, appealed Woodcock's decision to the FDA Commissioner, Dr. Robert Califf. Califf upheld Woodcock's decision on September 16, 2016.

In December 2016, Seife submitted his FOIA request to the FDA and HHS. At the same time, he requested expedited processing. On December 21, 2016, the FDA denied Seife's request for expedited processing. Seife appealed that denial administratively and, on April 25, 2017, the FDA denied his appeal.

C. ***The Proceedings Below***

On May 25, 2017, Seife commenced this lawsuit challenging the denial of expedited processing and what was tantamount to a constructive denial of his FOIA request. Soon after, Seife moved for partial summary judgment on expedited processing; following meet and confers, the FDA granted Seife's request for expedited processing. The parties also agreed to a schedule for producing documents responsive to a narrowed FOIA request. Two of the records Seife requested related to the clinical study reports: first, "[a]ll non-exempt portions of the narrative portion of the Clinical Study Report ("CSR") related to Study 201 and Study 202"; and, second, certain Study 201 and Study 202 tables, figures, and graphs as well as "protocols and protocol amendments; statistical analysis plans and plan amendments." Joint App'x at 2251-52.

On July 28, 2017, the FDA sent records, including the clinical study reports, to Sarepta for review. Throughout August 2017, Sarepta and the FDA

conducted rounds of adding or removing certain redactions. On September 15, 2017, Sarepta moved to intervene as a defendant, and the district court granted Sarepta's request. Between July 24, 2017, and December 8, 2017, the FDA produced approximately 45,000 pages to Seife, but redacted some pages pursuant to FOIA exemptions.

Seife challenged certain Exemption 4 redactions, including in parts of the clinical study reports and their appendices. The parties submitted cross-motions for summary judgment regarding those redactions, and Seife filed an additional motion to strike a declaration, that of Ian Estepan, submitted by Sarepta in connection with its motion for summary judgment. On March 27, 2019, the district court denied Seife's motion to strike and reserved judgment on the cross-motions for summary judgment pending the decision in *Food Marketing Institute v. Argus Leader Media*, a case involving Exemption 4 of FOIA which the Supreme Court had agreed to review, *see* 139 S. Ct. 915 (2019). At that time, the district court also ordered Sarepta to re-review its redactions to make sure all publicly available information had been given to Seife. Defendants ultimately produced unredacted versions of some previously redacted records. The Supreme Court decided *Argus Leader* on June 24, 2019.

On October 6, 2020, the district court issued its opinion granting Defendants' motion for summary judgment and denying Seife's motion for summary judgment. The district court concluded that Defendants' declarations demonstrated that the redacted information fell within Exemption 4 and that disclosure either was prohibited by law or would cause foreseeable harm to the interests protected by Exemption 4. It did so, however, without specifying what those protected interests were. Judgment was entered on October 6, 2020.

This appeal followed.

DISCUSSION

FOIA cases are often resolved by summary judgment. *See, e.g.*, *Grand Cent. P'ship, Inc. v. Cuomo*, 166 F.3d 473, 478 (2d Cir. 1999). Accordingly, the evidence in FOIA cases is typically limited to affidavits "in lieu of other documentary or testimonial evidence." *Long v. Off. of Pers. Mgmt.*, 692 F.3d 185, 190 (2d Cir. 2012). Summary judgment for the agency in a FOIA case is appropriate "when the affidavits describe the justifications for nondisclosure with reasonably specific detail, demonstrate that the information withheld logically falls within the claimed exemption, and are not controverted by either contrary evidence in the record nor by evidence of agency bad faith." *Wilner v.*

Nat'l Sec. Agency, 592 F.3d 60, 73 (2d Cir. 2009) (quoting *Larson v. Dep't of State*, 565 F.3d 857, 862 (D.C. Cir. 2009)).[5]

"We review a district court's grant of summary judgment in FOIA litigation *de novo*." *See Am. Civ. Liberties Union v. Nat'l Sec. Agency*, 925 F.3d 576, 588 (2d Cir. 2019). Additionally, we review a district court's evidentiary rulings for abuse of discretion. *See Lore v. City of Syracuse*, 670 F.3d 127, 155 (2d Cir. 2012).

As a threshold matter, Seife does not dispute on appeal that the redacted information falls within Exemption 4. *See* Pl.-Appellant's Reply Br. at 14 (stating that "this appeal is not about whether Exemption 4 applies.").[6] The

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[5] Seife neither suggests there was, nor offers evidence of, agency bad faith relating to his FOIA request.

[6] In any event, the information falls squarely within Exemption 4. Exemption 4 provides that an agency need not disclose "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). First, Sarepta is a person for purposes of Exemption 4. *See* 5 U.S.C. § 551(2) (defining a person as "an individual, partnership, *corporation*, association, or public or private organization other than an agency" (emphasis added)). Second, the information is commercial or financial in nature as relates to development of a new drug. Third, the information is "confidential." "At least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." *Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019). The record indicates that the information was available only to select individuals within Sarepta while outside parties signed a nondisclosure agreement, and that it was provided to the government under an assurance of privacy due to FDA regulations.

parties disagree, however, as to whether the information meets the additional burden imposed by the FIA. In relevant part, the FIA amended FOIA to add that "an agency shall withhold information under [FOIA] only if" either of the FIA's two prongs were met. 5 U.S.C. § 552(a)(8)(A). The two prongs are that: (1) the agency reasonably foresees that disclosure would result in harm to an interest protected by a FOIA exemption, 5 U.S.C. § 552(a)(8)(A)(i)(I), or (2) disclosure is prohibited by law, 5 U.S.C. § 552(a)(8)(A)(i)(II). Summary judgment for Defendants was thus proper if their affidavits described the justifications for the redactions with reasonably specific detail, disclosure would result in foreseeable harm to an interest protected by Exemption 4 or was prohibited by law, and Seife failed to present evidence to the contrary. *See Wilner*, 592 F.3d at 73.

We begin with the foreseeable harm requirement. Two questions are presented: first, what are the interests protected by Exemption 4; and, second, did the district court err in granting summary judgment on the basis that disclosure would result in foreseeable harm to such an interest?

A. ***The Interests Protected by Exemption 4***

In statutory interpretation, "a court's proper starting point lies in a careful examination of the ordinary meaning and structure of the law itself."

Food Mktg. Inst. v. Argus Leader Media, 139 S. Ct. 2356, 2364 (2019). That includes "reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). Our reading of a statute should "give effect, if possible, to every clause and word," *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (internal quotation marks omitted), with no provision "rendered superfluous," *United States v. Anderson*, 15 F.3d 278, 283 (2d Cir. 1994).

1. *Existing Interpretations*

Although this is a matter of first impression for the appellate courts, there are two primary competing district court interpretations of the interests protected by Exemption 4.

First, the district court for the District of Columbia has held that the interests protected by Exemption 4 are "the submitter's economic or business interests." *Ctr. for Investigative Reporting v. Customs and Border Prot.*, 436 F. Supp. 3d 90, 113 (D.D.C. 2019) (cleaned up). To reach that conclusion, the court considered all the terms in Exemption 4, including the words "confidential," "commercial," and "financial." The district court also held that for an agency to show foreseeable harm to the submitter's economic or business interests, it has to

demonstrate that disclosure would cause "genuine harm to the submitter's economic or business interests and thereby dissuad[e] others from submitting similar information to the government." *Id*. (cleaned up).

Second, the district court for the Northern District of California has taken a broader approach, holding that the interest protected by Exemption 4 is "the information's confidentiality--that is, its private nature." *Am. Small Bus. League v. Dep't of Def.*, 411 F. Supp. 3d 824, 836 (N.D. Cal. 2019) (emphasis omitted). In doing so, the court limited its analysis to the word "confidential," concluding that "under [*Argus Leader*], the plain and ordinary meaning of Exemption 4 indicates that" confidentiality is the protected interest. *Id.*

Not surprisingly, the parties in this case disagree as to which approach we should adopt. Taking his cue from the first approach, Seife argues that an agency must show harm through "diminution in the economic value of a submitter's intangible property" calculated in the same way as monetary damages. Pl.-Appellant's Br. at 18-19. Defendants, however, urge us to adopt the *American Small Business League* analysis, as they argue that "the interest protected by Exemption 4 is the confidentiality of the information itself." Defs.-Appellees' Br. at 26; *see* Intervenor-Def.-Appellee's Br. at 26 (arguing that

confidentiality is "an interest protected under the exemption"). As the district court recognized in *American Small Business League*, confidentiality is a broad interest; thus, "[d]isclosure would necessarily destroy the private nature of the information, no matter the circumstance." 411 F. Supp. 3d at 836.

2. *Analysis*

We hold that the interests protected by Exemption 4 of FOIA are the commercial or financial interests of the submitter in information that is of a type held in confidence and not disclosed to any member of the public by the person to whom it belongs. We examine the ordinary meaning and structure of Exemption 4, looking at the words themselves, the specific context in which the words appear, "and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. at 341; *see also Abuelhawa v. United States*, 556 U.S. 816, 819 (2009) (explaining that "statutes are not read as a collection of isolated phrases").

Exemption 4 covers "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). For purposes of this case, Exemption 4 protects information that is "commercial or financial," "obtained from a person," and "confidential." All these clauses limit the scope of Exemption 4 and thus define its protected

interests, as we must "give effect, if possible, to every clause and word." *Walker*, 533 U.S. at 174.

The plain text of Exemption 4 indisputably protects confidential information. But it protects only certain confidential information, namely, confidential information that is commercial or financial in nature. The statute therefore contemplates harm specifically to commercial or financial interests. Furthermore, the confidential commercial or financial information must be obtained from a person. That requirement indicates the contemplated harm is to the person from whom the agency receives the confidential information -- that is, the submitter. Thus, the protected interests are the submitter's commercial or financial interests, and the FIA's foreseeable harm requirement refers to harm to the submitter's commercial or financial interests.[7]

[7] We reject Seife's proposition that harm must be "measured by the diminution in the economic value of the information to the submitter," Pl.-Appellant's Br. at 27, because we find no support for that reading in the statutory text. Furthermore, a court is well-equipped, when looking at the evidence in the record, to foresee whether a specific identifiable harm to a submitter's commercial or financial interests will occur without being restricted to finding a measurable diminution in economic value. *See* S. Rep. No. 114-4 (2015), *as reprinted in* 2016 U.S.C.C.A.N. 321, 328 ("The standard mandates that an agency may withhold information only if it reasonably foresees a specific identifiable harm to an interest protected by an exemption.").

The "specific context in which that language is used" and the "broader context of the statute as a whole" reinforce our conclusion. *Robinson*, 519 U.S. at 341. The FIA amended FOIA to add an independent statutory requirement that an agency must meet to withhold information. The specific context of the language used makes clear that, at least in Exemption 4 cases, the FIA requirement poses an additional burden on the withholding agency. Congress explicitly wrote that the FIA does not apply to information withheld under Exemption 3. 5 U.S.C. § 552(a)(8)(B) ("Nothing in this paragraph requires disclosure of information that is . . . otherwise exempted from disclosure under [Exemption 3]."). But the statute says nothing about excluding Exemption 4.

Defendants argue that we should look only at the word "confidential" and hold that the interest protected by Exemption 4 is simply "confidentiality." If we were to accept that interpretation, any and all confidential information would be exempt from disclosure, for disclosure "would necessarily destroy the private nature of the information" and confidentiality -- the interest purportedly protected by Exemption 4 -- would necessarily be harmed. *Am. Small Bus. League*, 411 F. Supp. 3d at 836.

Defendants' position is belied by both the structure of the statute and common sense. Congress expressly enacted the FIA to address situations where information would fall within an exemption and yet no harm would result from disclosure, emphasizing that in those circumstances the information must be disclosed. *See* S. Rep. No. 114-4 (2015), *as reprinted in* 2016 U.S.C.C.A.N. 321, 322-24 (stating that agencies were "relying on these discretionary exemptions . . . even though no harm would result from disclosure"). The foreseeable harm requirement must be met independently from the elements of the exemption; otherwise, the FIA adds nothing.

In arguing that the interest protected by Exemption 4 is the "confidentiality of the record maintained by the person who submitted that record to the government," Defs.-Appellees' Br. at 29, Defendants rely on *Argus Leader*. The crux of their argument is that the Supreme Court squarely held in *Argus Leader* that the interest protected by Exemption 4 is confidentiality. *See id*. at 29 ("[*Argus Leader*] thus makes clear that the 'interest protected by' Exemption 4 is . . . the confidentiality of the record."). We are not persuaded.

Defendants' reliance on *Argus Leader* is unfounded. In *Argus Leader*, the Supreme Court answered the question whether the term "confidential" in

Exemption 4 should be given its ordinary meaning. *Argus Leader Media*, 139 S. Ct. at 2363. The Supreme Court did not once mention the FIA or what interests Exemption 4 protects, and for good reason -- the underlying FOIA request in that case was filed prior to the FIA's effective date.

Here, we answer an entirely different question -- rather than consider the meaning of an isolated term, we consider which interests are protected by Exemption 4 as a whole. That is a question the Supreme Court neither answered nor had cause to answer in *Argus Leader*. At bottom, *Argus Leader* interpreted one word. While the focus on confidentiality was appropriate in that context -- where the only question was the definition of "confidential" -- it is not appropriate here, where we must read the statute in its entirety. In fact, as Defendants ignore, *Argus Leader* itself acknowledged commercial or financial limitations to confidentiality in the terms of Exemption 4. *Compare id*. at 2364 ("Exemption 4 protects information 'which would customarily not be released to the public by the person from whom it was obtained' *such as 'business sales statistics' and 'customer lists'*" (quoting S. Rep. No. 813, 89th Cong., 1st Sess., 9 (1965)) (emphasis added)) *with* Defs.-Appellees' Br. at 29 (omitting the emphasized portion).

In conclusion, we hold that the interests protected by Exemption 4 are the submitter's commercial or financial interests in information that is of a type held in confidence and not disclosed to any member of the public by the person to whom it belongs. An agency in a FOIA case can therefore meet the foreseeable harm requirement of the FIA by showing foreseeable commercial or financial harm to the submitter upon release of the contested information.

B. ***Summary Judgment***

Thus, to be entitled to summary judgment, Defendants' submissions had to "describe the justifications for nondisclosure," that is, why the release of the information would harm Sarepta's commercial or financial interests, in "reasonably specific detail." *Wilner*, 592 F.3d at 73 (quoting *Larson*, 565 F.3d at 862). Moreover, the showing of harm to Sarepta's commercial or financial interests could not be controverted by contrary evidence in the record. *See id*.

a. ***Affidavits in the Record***

In support of their motions for summary judgment, Defendants submit primarily two declarations from Ian Estepan and two declarations from Nancy Sager. Estepan is the Chief of Staff and Head of Corporate Affairs at Sarepta and has experience in healthcare investing related to the development of

promising drug candidates, particularly therapies for patients with DMD.[8] His declarations describe in specific detail how the information requested by Seife could be used by Sarepta's competitors to take research and development shortcuts, develop studies using Sarepta's data, or predict Sarepta's future moves. Sager is the Director of the Division of Information Disclosure Policy in the FDA. Her declarations reference Estepan's and ultimately conclude that the "unpublished details of Sarepta's clinical studies . . . if released, would cause competitive harm to Sarepta." Joint App'x at 2257.

In support of his motion for summary judgment, Seife submits three declarations. The first is from Dr. Peter Lurie, the President of the Center for Science in the Public Interest and former Associate Commissioner for Public Health Strategy and Analysis at the FDA. The second is from Dr. Diana M.

[8] Although Seife argues that the district court should have excluded Estepan's declaration because it was "neither based on personal knowledge nor within [his] expert competence," Pl.-Appellant's Br. at 47, we disagree. Although Estepan is not a scientist or a doctor, his fifteen years of healthcare investigation, regular reviews of the scientific DMD landscape, and consultations with scientific, medical, and technical personnel mean that he is competent to testify about the "competitive harms that the disclosures at issue could cause," and does so from personal knowledge. Joint App'x at 87. Accordingly, we find that the district court did not abuse its discretion by considering the declaration.

Zuckerman, the President of the National Center for Health Research. The third is from Seife himself.

b. ***Foreseeable Harm***

We first conclude that Defendants presented sufficient evidence, in reasonably specific detail, to establish foreseeable harm to Sarepta's commercial or financial interests. Estepan's declarations describe how the information could be used to develop studies for other exon-skipping drugs, used in competitors' head-to-head trials, or be informative as to Sarepta's future clinical endpoint research. Even Seife's evidence acknowledges that the information Seife seeks would foreseeably cause harm to Sarepta. When discussing clinical study results, for example, Lurie writes that the information has a "small incremental value to competitors." *Id.* at 303.

Furthermore, we do not conduct our analysis in a vacuum. The pharmaceutical industry is, of course, highly competitive. Development of new pharmaceutical drugs is a long and arduous process -- research for Exondys 51 spanned many years, with the development of procedures for Study 201 and Study 202 alone taking three years, and the FDA approval process taking nine years. The big picture thus further supports Defendants' contentions that

Sarepta's commercial or financial interests would be foreseeably harmed by disclosure of information it developed and gathered, Sarepta's competitors would benefit from disclosure, and a benefit to competitors would necessarily be a detriment causing harm to Sarepta.

Seife failed to present any evidence that meaningfully controverts Defendants' showing of foreseeable harm. As a threshold matter, Seife argues that none of Defendants' declarations can successfully show harm because there is "substantially similar public information." Pl.-Appellant's Br. at 33. Thus, his argument goes, the similarity of the publicly available information means that Sarepta cannot suffer harm to its commercial or financial interests by the disclosure of information that is essentially the same. Seife's argument falls short. A FOIA decision is "evaluated as of the time it was made and not at the time of a court's review." *Am. Civ. Liberties Union*, 925 F.3d at 602 (internal quotation marks omitted). Seife does not specify which, if any, of the allegedly substantially similar data was published at the time he filed his FOIA request in December 2016.

Seife also contends that the declarations he submitted serve as contrary evidence in the record "refut[ing] Sarepta's . . . claims that disclosure of

the information sought would foreseeably harm Sarepta's [protected interest]." Pl.-Appellant's Br. at 20.

We disagree. Only Lurie's declaration addresses foreseeable harm to Sarepta's commercial or financial interests, and it does not dispute that Sarepta would suffer foreseeable harm from disclosure of the information at issue.[9] Instead, Seife's evidence at most challenges the degree of commercial or financial harm to Sarepta, rather than that such harm would result.

In addition, much of Seife's evidence consists of broad, hedging statements. For example, Lurie writes that disclosing endpoint data is "*unlikely* to be commercially appealing," Joint App'x at 301 (emphasis added), or that competitors who may be interested in clinical study procedures "are *presumably* designing different drugs," *id*. at 298-99 (emphasis added). Seife thus fails to controvert Defendants' specific assertions that the information could be used to

[9] Zuckerman's declaration discusses only irregular aspects of Exondys 51's approval process and public policy reasons for releasing the information at issue. Seife's declaration is limited to those topics with additional testimony on redacted information substantially similar to public information, an argument we have already rejected. The dispute within the FDA over the approval of Exondys 51 is concerning. Defendants, however, have already produced over 45,000 pages of Seife's requested documents. And, as a matter of law, summary judgment for Defendants is warranted unless Seife's evidence controverts Defendants' claims of harm to Sarepta's business interests.

develop studies for other exon-skipping drugs, in competitors' head-to-head trials, or as information regarding Sarepta's future clinical endpoint direction in ways that would harm Sarepta's competitive interests.

In all, Defendants have shown that it was reasonably foreseeable that Sarepta would suffer harm to its commercial or financial interests if any of the information Seife seeks were released. Seife neither successfully disputes that showing with his own evidence -- much less shows a genuine dispute of material fact -- nor offers evidence of bad faith in the provision of Defendants' declarations. Seife was thus not entitled to an evidentiary hearing or additional discovery. *See Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 812 (2d Cir. 1994) ("[I]f the agency's submissions are adequate on their face . . . the district court may forgo discovery and award summary judgment on the basis of affidavits." (internal quotation marks omitted)).

While Seife makes numerous policy arguments favoring disclosure, FOIA does not have an exception for cases where public health may be served by disclosure. *See Argus Leader*, 139 S. Ct. at 2366. We conclude that Defendants have made the requisite showing for summary judgment on the foreseeable harm prong of the FIA and affirm the district court's judgment on that ground.

As we are satisfied that Defendants have shown the first prong of the FIA, we need not address the alternative prong -- whether disclosure is prohibited by law.

CONCLUSION

For the reasons set forth above, we hold that the interests protected by Exemption 4 are the submitter's commercial or financial interests in information that is of a type held in confidence and not disclosed to any member of the public by the person to whom it belongs. Defendants' declarations show that release of the information Seife seeks would foreseeably harm Sarepta's interests and Seife does not raise a genuine dispute as to that showing. Accordingly, the district court's grant of summary judgment for Defendants and denial of summary judgment for Seife is AFFIRMED.