

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 TARCYNKA, 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

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