No. 18-481

IN THE

Supreme Court of the United States

FOOD MARKETING INSTITUTE,
Petitioner,

v.

ARGUS LEADER MEDIA, D/B/A ARGUS LEADER,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF OF *AMICUS CURIAE* BIOSCIENCE ADVISORS, INC. IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS CURIAE[1]

BioScience Advisors, Inc. ("BioSci") is a small consulting firm whose principal, Mark Edwards, regularly acts as an advisor and negotiator on behalf of companies in the pharmaceutical and biotechnology industries (the "BioPharma Industry"). BioSci provides information, interpretation, and advice on technology, compound or product development and commercialization agreements. As part of its consulting services, BioSci obtains, organizes and provides market data from development, co-development and commercialization agreements.

Since many BioPharma companies are SEC-reporting companies, BioSci collects agreements and information from SEC filings.Under Mr. Edwards' supervision, BioSci's database, BioSciDB,[2] contains copies of approximately 25,000 license, development, co-development, joint venture, distribution, asset purchase and other arm's-length agreements that

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[1] Counsel for all parties consented to the filing of this brief. Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus* or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

[2] Prior to the creation of BioSciDB, Mr. Edwards was involved in the creation of other industry databases, including the Recap Corporate Alliances Database and RecapIQ.

have been publicly filed with the SEC. Where companies request confidential treatment for certain information, BioSci first reviews redacted copies. Subsequently, BioSci works to obtain unredacted copies. It has obtained more than 15,000 unredacted agreements, with the majority obtained via Freedom of Information Act (FOIA) requests. BioSciDB has more than one hundred subscribers, primarily companies and research institutions, including Amgen, Cedars Sinai, Childrens Hospital of Philadelphia, Cornell University, Dana Farber, Gilead Sciences, Merck, Mount Sinai, Ohio State University, and Roche.

The BioPharma industry appears to appreciate the work of BioSci and Mr. Edwards. In 2008, Mr. Edwards was awarded a Lifetime Achievement Award by the American Liver Foundation for "two decades of leadership, thoughtful insights and detailed analysis of the biotechnology industry." Mr. Edwards is currently on the boards of directors of The Scripps Research Institute and AcelRx Pharmaceuticals. Mr. Edwards has been a retained consultant for more than 50 BioPharma companies and universities, including Amgen, Bayer, Boehringer Ingelheim, Brigham Young University, Bristol-Myers Squibb, Elan, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Max Planck, Pfizer, Roche, State University of New York, and UCLA.

To the extent that the Court addresses the scope of Exemption 4,[3] BioSci, and as argued herein—the BioPharma industry itself—have an interest in the outcome of this proceeding. BioSci asks that the Court construe Exemption 4 in a reasonable manner, providing for the continuing appropriate balancing of confidentiality interests with the broader interests of the economy to enable accurate disclosure and access to information.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

If the Court reaches the merits of Exemption 4, it should reject Petitioner's arguments. BioSci would be negatively affected by this Court adopting Petitioner's preferred construction. BioSci provides a valuable service to the drug development industry, and those services would not be possible without the current well-functioning and balanced FOIA system. That system allows BioSci to lawfully collect key transaction data from historical transaction documents submitted to the SEC. This key data includes information like royalty rates, upfront payment, milestones, and alliance terms. Some commentators on the U.S.'s world-leading status in pharmaceutical innovation credit the availability of such data. Furthermore, BioSci's curation of this BioPharma industry data does

[3] It appears that Amici's position on Exemption 4 may be relevant only if this Court finds that Petitioner has Article III standing, and further if the Court rules as requested by Petitioner regarding the applicability of 7 U.S.C. § 2018(c). Amici takes no position on these threshold issues.

not hurt individual industry actors, but rather benefits the entire industry by facilitating good decision-making, enhancing and confirming the importance of existing disclosure laws, and avoiding less desirable services that would emerge and thrive under a lasting secrecy regime.

Through the FOIA processes described, BioSci provides a valuable service to the drug development industry. SEC-reporting BioPharma companies usually request confidential treatment for certain business information in agreements filed with the SEC. BioSci initially collects redacted versions of SEC-filed agreements and later attempts to secure less-redacted versions through FOIA requests. Under current law, SEC grants of confidentiality are time-limited unless the filer continues to request confidentiality and provides substantiation. Furthermore, reporting companies often choose to not renew requests for confidential treatment, and/or decline to oppose FOIA requests. A company actor may and often does consider certain deal information "confidential" at the time of the original SEC submission. But in the fast-moving BioPharma industry, within an often short period of time, that same industry actor often considers that same deal information to be non-confidential or irrelevant. Rationales for this shift in position vary, and include technological obsolescence, or changes in the reporting company's relationship to that technology.

That formerly confidential data may be stale to the submitter, but its use as data for the entire industry is invaluable. BioSciDB is built upon FOIA requests seeking once-confidential data. BioSciDB contains

copies of approximately 25,000 license, development, co-development, joint venture, distribution, asset purchase and other arm's-length agreements. Companies, universities and other interested parties use BioSciDB to inspect, analyze, share and enhance best practices in negotiating, structuring, and managing alliances.

BioSci agrees with Respondent's argument that "confidential" should continue to be construed to mean information that is confidential in nature based on objective harm of disclosure. This approach acknowledges that the plain meaning of the term cannot be divined without some reference to context. As such, the best reading of Exemption 4's statutory language is that it requires a showing of likely competitive harm upon disclosure. Thus, BioSci requests that the Court, if it reaches the question of Exemption 4, decline to grant Petitioner's request for a construction of the term "confidential" that is disconnected from actual adverse consequences to a business or its competitive position.

ARGUMENT

I. BioSci Relies Upon Current FOIA Jurisprudence and Practice in Conducting Its Business.

BioSci is heavily reliant upon FOIA requests to obtain more complete and accurate historical data to populate BioSciDB. BioSci files approximately 30 FOIA requests per week, 52 weeks per year.

BioSci's process for gathering transaction information includes several distinct steps. First, by monitoring press releases, BioSci identifies an announced or completed arms-length BioPharma relationship or transaction, such as a license, acquisition, or supply agreement. BioSci then collects public statements on the transaction, including SEC-filed contracts which are often redacted. BioSci subsequently requests through FOIA unredacted or less-redacted versions of what was earlier filed.

Of approximately 25,000 discrete SEC-filed contracts currently in BioSciDB, 5,500 (22%) were filed unredacted, 9,300 (38%) were filed redacted, and 9,900 (40%) were obtained via FOIA requests. Not counting amendments and acquisitions, BioSciDB presently contains approximately 16,000 discrete SEC-filed contracts covering de novo arms-length relationships. Of these, 2,700 (16%) were field unredacted, 6,400 (39%) were filed redacted, and 7,200 (44%) were obtained via FOIA requests.

Thus, in the absence of a functional FOIA process for the eventual release of contract data initially designated as confidential, 75-80% of BioPharma deals would be known on the basis of incomplete disclosure only. By contrast, with FOIA functioning as it currently does, approximately 60% of all deals are accessible for analysis based on full disclosure.

Given the importance of FOIA requests to BioSci, a change in the law with the effect of broadening the scope of exemption 4 would materially interfere with BioSci's work.

II. The BioPharma Industry Benefits from Access to the Important Historical Data Provided by BioSci's FOIA Requests.

The business prospects and research pipelines of BioPharma companies face substantial uncertainty due to the inherent risks and substantial costs associated with new drug development projects, including human testing,[4] regulatory approval and competitive positioning In addition, the biopharmaceutical research and development process often lasts a decade or more.[5]

These attributes mean that companies hoping to be successful in the BioPharma space must raise large amounts of capital over an extended period of time. The liquidity necessary for these huge projects, and indeed a vibrant capital markets system generally, requires transparency. Some industry observers have credited the open disclosure system within the U.S. as a rationale for the number of industry-leading companies based in the U.S. Relatedly, a factfinding group in the UK found that its biotechnology sector

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[4] *See* J. DiMasi, H. Grabowski, R. Hansen, Innovation in the Pharmaceutical Industry, 47 J. of Health Econ. 20, 23 (2016) ("The industrial R&D process is marked by substantial financial risks, with expenditures incurred for many development projects that fail to result in a marketed product.").

[5] J. DiMasi, R. Hansen, H. Grabowski, *The Price of Innovation: New estimates of Drug Development Costs*, 22 J. of Health Econ. 151, 153 (2003).

lacked vibrancy in large part due to lack of transparency and a cultural bias in favor of secrets.

Without the detailed historical industry information made available by BioSciDB through consistent FOIA requests, investors and participants in BioPharma transactions would 1) make less informed decisions, possibly on the basis of misleading information; and 2) pursue less desirable information access alternatives.

A. The FOIA Process As Presently Administered by the SEC Advances the Securities Laws' Goals of Disclosure, and Operates as an Important Check on False Press Releases.

Given the aforementioned attributes—extreme expense, length, and uncertainty—the drug development industry is heavily reliant on large-scale investment from a variety of public and private sources. Thus, the securities laws are of particular importance, as companies typically must raise funds both initially and also periodically throughout a project. U.S. securities laws "put the burden of telling the whole truth on the seller"[6] and, of course, emphasize "disclosure, again, disclosure, and still more disclosure."[7] Market efficiency requires accuracy.

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[6] A. Schlesinger, Jr., The Coming of the New Deal 441 (1958) (quoting Franklin D. Roosevelt asking Congress for new securities laws in 1933).

[7] L. Loss, Securities Regulation 21 (2d ed. 1961).

In particular, BioPharma press releases are often the subject of securities enforcement and lawsuits.[8] BioPharma companies are known to push the limits of disclosure laws, perhaps because of the high-risk and capital-intense nature of the business.[9] In short, executives face ongoing extreme pressure to promote the technology to investors. Without the influx of capital accompanying aggressive promotion, the technology—regardless of scientific promise—will die on the vine (as 90% of projects do).

Certainly, as to SEC-filing companies, the SEC receives access to the unredacted filings which contain information that may undermine a corporate statement. However, the SEC does not have unlimited resources. Furthermore, other actors—including state regulators, shareholders, industry watchers, stock analysts and even competitors—all regularly play roles in addressing possible misstatements. For

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[8] *E.g.*, SEC Press Release No. 2018-199 (Sept. 18, 2018) (describing penalties imposed on Colorado-based biopharmaceutical company because company press releases and other investor communications "stated that drug was effective 60 percent of the time, far higher than suggested by actual results available internally").

[9] *See* A. Schuhmacher, O. Gassmann, M. Hinder, Changing R&D Models in Research-based Pharmaceutical Companies. 14 J. of Translational Med. 105, 105-07 (describing the law success rates and high costs of drug projects).

instance, shareholders—often the most attentive of any of the foregoing—can bring private actions under both federal[10] and state securities regimes.[11] Thus, where information is more available, and more particularly where corporate actors know that true information is likely to be made available to a wider audience—then those corporate actors will act with a heightened awareness of the risks of inadequate, false or misleading disclosure.

B. Where FOIA Access is Weakened, BioPharma Industry Actors Will Increase Reliance on Alternative Confidential Information Providers Including Lawyers and Investment Bankers.

If BioSci's FOIA access opportunities to key historical data are undermined in the manner proposed by Petitioner, the BioPharma industry would lose an important information source. No doubt, the industry would adapt. The most likely adaptation would be enhanced importance, and evolved roles, of

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[10] *E.g.*, *Superintendent of Ins. of State of N. Y. v. Bankers Life & Cas. Co.*, 404 U.S. 6, 13 n. 9 (1971) ("It is now established that a private right of action is implied under s 10(b).")

[11]; *E.g.*, Utah Code Ann. § 61-1-1; Utah Code Ann. § 61-1-22; *Gohler v. Wood*, 919 P.2d 561, 565 (Utah 1996) (holding that Utah Code Annotated § 61-1-22 "creates an express private cause of action for violations of section 61-1-1(2).").

the "Secret Priesthood"—law firms and investment banks with access to industry secrets that serve as advisors to various companies within the BioPharma Industry.

These advisors of course already act as an existing information source. Part of their client pitch—sometimes subtle, sometimes less so—is that they advised on prior deals and thus have insight into confidential historical data as to what constitutes "market" on a given deal term. While express conveyance of prior client confidential data to a current client would violate professional ethics,[12] some conveyances may operate in a less-than-express manner that may not violate professional rules. Furthermore, even where conveyances are proscribed by professional rules, violations may never be discovered.

The expertise, experience and importance of such professionals is obviously valuable. However, if the primary rationale for using such professionals is to utilize their inevitable knowledge of confidential data from prior clients and prior transactions—because that data is not available anywhere else—that

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[12] *See, e.g.*, Canon 4, ABA Code of Professional Responsibility ("A lawyer should preserve the confidences and secrets of a client."); *see also* New York State Rules of Professional Conduct, Rule 1.6 (McKinney 2019) ("A lawyer shall not knowingly reveal confidential information, as defined in this Rule, or use such information to the disadvantage of a client or for the advantage of the lawyer or a third person, unless [listing specific exceptions.]"

rationale places stress on significant ethical and professional boundaries.[13]

III. Existing Exemption 4 Practice Operates a Reasonable Balance for Competing Interests

Under Exemption 4, and the implementing rules and regulations, SEC filers are entitled to a reasonable process that provides an opportunity for the filer to seek and obtain, through sequential applications, time-unlimited protection of confidential information. At the same time, the system also allows for the presumptive expiration of the confidentiality designation, which ultimately benefits the entire industry.

Pursuant to the SEC's FOIA regulations, a reporting company "can request that the information not be disclosed pursuant to a request under the [FOIA] . . . for reasons of personal privacy or business confidentiality, or for any other reason permitted by Federal law."[14] The SEC's regulations further establish a balanced process for consideration of "confidential treatment requests." This process includes: opportunities for the reporting company to submit a written sub-

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[13] *See, e.g.*, *Med. Diagnostic Imaging v. CareCore Nat.*, 542 F. Supp. 2d 296, 315 (S.D.N.Y. 2008) ("The principle way in which the integrity of the adversary process can be undermined, in the context of a violation of Canon 4, is by the use of a former client's confidences to the new client's advantage.").

[14] 17 C.F.R. § 200.83(a), (c).

stantiation of the request; preliminary decisions communicated from the Commission's Office of FOIA Services; opportunities for supplemental arguments with respect to the preliminary decision, and a final decision from the Office of FOIA Services.[15] Furthermore, the SEC provides for both an internal appeal process and judicial review.[16]

In practice, the current regime does not appear to be unfairly weighted in favor of requesters like BioSci. SEC-reporting companies have straightforward opportunities under the implementing regulations and rules to oppose a FOIA request, and to submit requests to extend the applicable time frame for confidential treatment. As one example, BioSci submitted a FOIA request for an unredacted Form 10-Q filed by Immunogen, Inc. on May 7, 2009. This 10-Q included as an exhibit redacted amendments to a 2000 License Agreement with Genentech.[17] The license agreement related to a drug eventually approved as the breast cancer treatment, Kadcyla. For years after the 2009 filing, pursuant to SEC Rule 24b-2, Immunogen submitted multiple applications to the SEC requesting continuing confidential treatment for the information excluded from the license agreement. In response to

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[15] 17 C.F.R. § 200.83.

[16] 17 C.F.R. § 200.83(d),(e); *Chrysler Corp. v. Brown*, 441 U.S. 281, 317 (1979).

[17] ImmunoGen, Inc., Quarterly Report (Form 10-Q), Exh. 10.1 (May 7, 2009).

these applications, the SEC first extended the confidentiality timeline through May 9, 2012, then again through February 8, 2019, and then again through February 8, 2026.[18] This one example shows that companies with supportable concerns about confidentiality are able to continue to keep certain information confidential. However, at least under the existing law, for each extension, it may be presumed that Immunogen presented the SEC with some substantiation for its request for continuing confidential treatment.

In short, changing the construction of the statutory term "Confidential" appears to be an unnecessary shift in favor of the SEC-filer, particularly given that as shown in the example above, an SEC filer already has sufficient tools to interact with the SEC and make a case for ongoing protection of confidential information with ongoing relevance. Furthermore, where such information is made public, in the vast majority of cases there is no competitive harm because the specific relevance of the information has expired. Yet as shown by BioSci, that information can be marshaled

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[18] June 25, 2009 SEC Order Granting Confidential Treatment Under the Securities Exchange Act of 1934, ImmunoGen, Inc., File No. 000-17999 CF No. 23628; May 8, 2012 SEC Order Granting Confidential Treatment Under the Securities Exchange Act of 1934, ImmunoGen, Inc., File No. 000-17999 CF No. 27869; March 18, 2019 SEC Order Granting Confidential Treatment Under the Securities Exchange Act of 1934, ImmunoGen, Inc., File No. 000-17999 CF No. 37158.

as part of industry data to enhance the functioning of an important industry.

CONCLUSION

Adopting the Petitioner's proposed definition of "Confidential" would adversely affect the BioPharma Industry. BioSci fills an important niche in the BioPharma consulting space because of its extensive knowledge of historical biopharmaceutical deal terms. BioSci helps its clients understand the marketplace and make more informed decisions, and BioSci's services are dependent upon the existing well-balanced FOIA regime. For these reasons, important policy objectives for public reporting companies will be served by this Court continuing to follow its prior admonitions that FOIA Exemptions be construed narrowly. Thus, to the extent the Court reaches the issues involving construction of Exemption 4, the Court should affirm the judgment of the Court of Appeals.

Respectfully submitted,

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March 25, 2019