UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,

Petitioner

v.

HALOZYME, INC.,

Patent Owner

Case PGR2025-00003 | U.S. Patent No. 11,952,600
Case PGR2025-00004 | U.S. Patent No. 12,018,298
Case PGR2025-00006 | U.S. Patent No. 12,152,262
Case PGR2025-00009 | U.S. Patent No. 12,123,035

quinn emanuel
quinn emanuel urquhart & sullivan, llp

Halozyme

Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

Halozyme EX2501
Merck v. Halozyme
PGR2025-00004

Merck & Co., Inc. Is A Real Party-in-Interest

Correct RPI Must Be Named

"Because petitioner here has failed to name all real parties-in-interest, the Petitions have not met the requirements of 35 U.S.C. § 312(a)(2), and, therefore, are incomplete and cannot be considered."

Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc., IPR2014-00440, Paper 68 at 24 (PTAB Aug. 18, 2015) (precedential, except for § II.E.1).

"[o]nly **precisely-identified real parties in interest** are entitled to have their petitions considered, 35 U.S.C. 312(a),"

"Petitioner's failure to provide clarity as to its actual identity is fatal to its petitions."

Yangtze Memory Techs., Ltd, v. Micron Tech., Inc., IPR2025-00098, Paper 38 at 5-6 (PTAB Jan. 15, 2026) (designated informative Jan. 16, 2026).

PGR2025-00003 Petition at 6; Patent Owner's Motion to Terminate ("MTT") at 4-8

Legal Standard For RPI

Determining whether a non-party is an RPI "**demands a flexible approach** that takes into account both equitable and practical considerations, with an eye toward determining whether the non-party is a clear beneficiary that has a preexisting, established relationship with the petitioner."

Applications in Internet Time, LLC v. RPX Corp., 897 F.3d 1336 at 1351 (Fed. Cir. 2018);
RPX Corp. v. Applications in Internet Time, LLC, IPR2025-01750, Paper 128 at 7-8 (P.T.A.B. Oct. 2, 2020).

Control or opportunity to control the proceedings - whether a non-party has the "control or opportunity to control that might reasonably be expected between two formal coparties." *Corning* at 15.

Funding the proceedings can also be considered. *Corning* at 14.

Blurred lines - whether Petitioner's actions "have blurred sufficiently the lines of corporate separation with [an unnamed related entity], such that [the entity] could have controlled the filing and participation" of the AIA proceeding.

Corning at 15 (citing *Zoll Lifecor Corp. v. Philips Elec. N. Am. Corp.*, Case IPR2013-00606, Paper 13 at 10 (PTAB Mar. 20, 2014).

Clear beneficiary - "who, from a 'practical and equitable' standpoint, will benefit from the redress" that the proceeding might provide. *RPX* at 8 (citing *AIT*, 897 F.3d at 1349).

PGR2025-00003 Petition at 6; MTT at 4-8

Merck & Co., Inc. Informed The SEC That It **Filed** The PGR Petitions

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

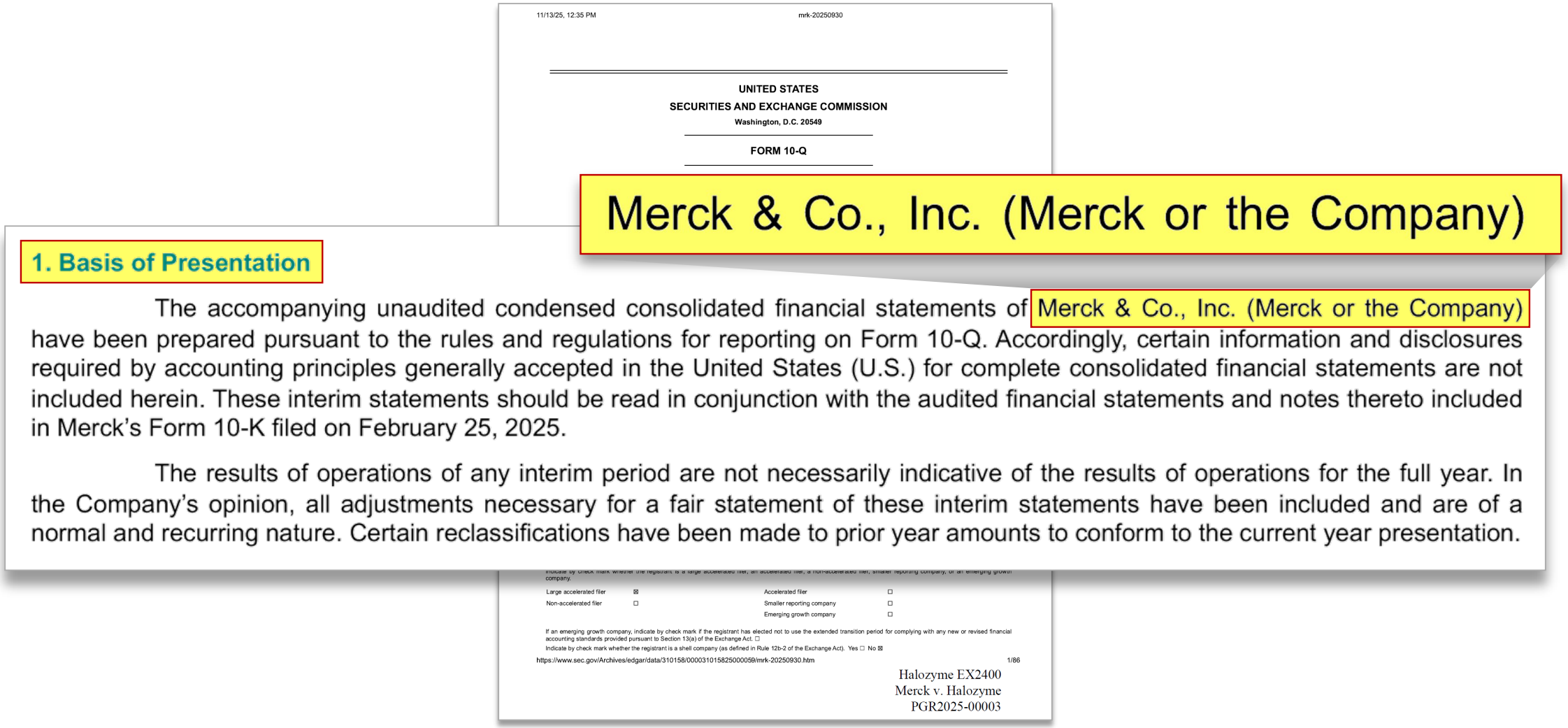
(Exact name of registrant as specified in its charter)

New Jersey	**22-1918501**
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)

126 East Lincoln Avenue
Rahway New Jersey 07065
(Address of principal executive offices) (zip code)

EX. 2400 (Merck & Co., Inc., Nov. 5, 2025 10Q SEC Filing) at 1; MTT at 8-10

Merck & Co., Inc. Informed The SEC That It **Filed** The PGR Petitions



11/13/25, 12:35 PM mrk-20250930

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

Merck & Co., Inc. (Merck or the Company)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Merck & Co., Inc. (Merck or the Company) have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by accounting principles generally accepted in the United States (U.S.) for complete consolidated financial statements are not included herein. These interim statements should be read in conjunction with the audited financial statements and notes thereto included in Merck's Form 10-K filed on February 25, 2025.

The results of operations of any interim period are not necessarily indicative of the results of operations for the full year. In the Company's opinion, all adjustments necessary for a fair statement of these interim statements have been included and are of a normal and recurring nature. Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

company.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

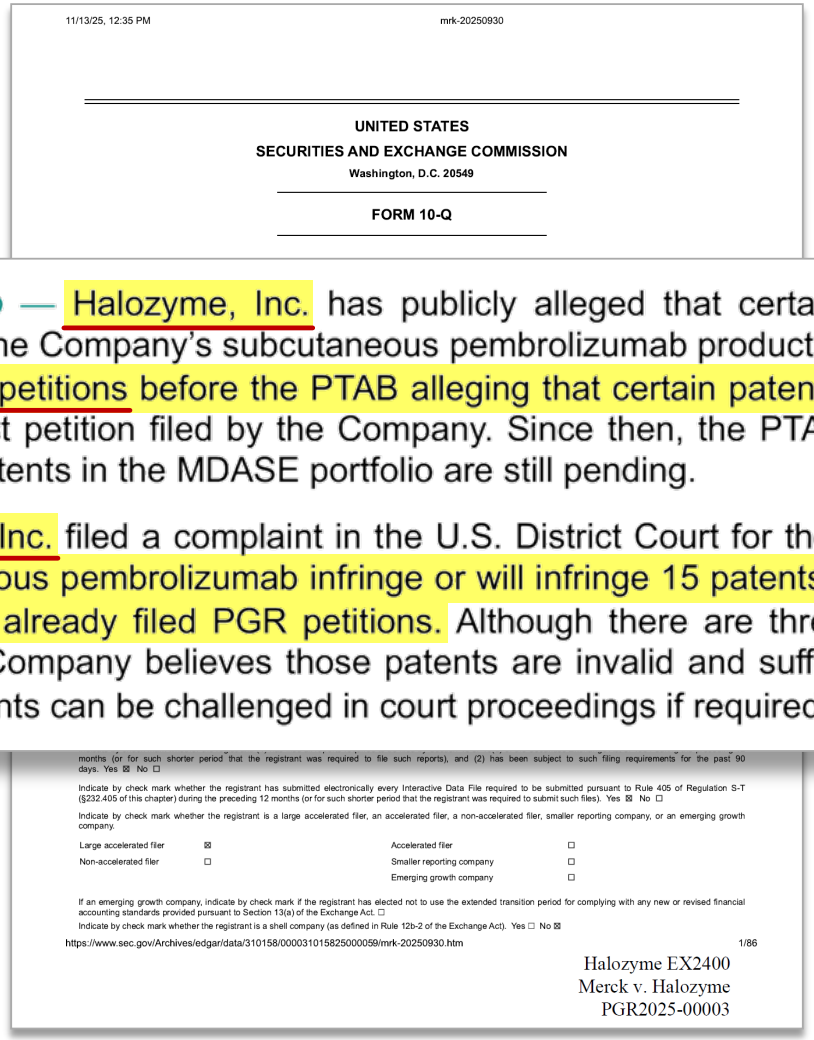
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

https://www.sec.gov/Archives/edgar/data/310158/000031015825000059/mrk-20250930.htm 1/86

Halozyme EX2400
Merck v. Halozyme
PGR2025-00003

EX. 2400 (Merck & Co., Inc., Nov. 5, 2025 10Q SEC Filing) at 7; MTT at 8-10

Merck & Co., Inc. Informed The SEC That It **Filed** The PGR Petitions


11/13/25, 12:35 PM mrk-20250930

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

Subcutaneous Pembrolizumab — Halozyme, Inc. has publicly alleged that certain patents in its modified hyaluronidase (MDASE) portfolio cover an ingredient in the Company's subcutaneous pembrolizumab product. In November 2024, the Company began filing a series of post grant review (PGR) petitions before the PTAB alleging that certain patents in the MDASE portfolio are invalid. On June 2, 2025, the PTAB instituted the first petition filed by the Company. Since then, the PTAB also instituted ten additional petitions. Institution decisions on three additional patents in the MDASE portfolio are still pending.

On April 24, 2025, Halozyme, Inc. filed a complaint in the U.S. District Court for the District of New Jersey alleging that the Company's activities related to subcutaneous pembrolizumab infringe or will infringe 15 patents belonging to the MDASE portfolio, 12 of which are the subject of the Company's already filed PGR petitions. Although there are three patents that were not and cannot be challenged using the PGR process, the Company believes those patents are invalid and suffer from the same defects as the patents currently being challenged and those patents can be challenged in court proceedings if required.

months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

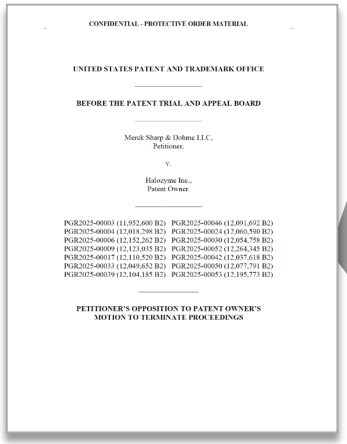
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

https://www.sec.gov/Archives/edgar/data/310158/000031015825000059/mrk-20250930.htm 1/86

Halozyme EX2400
Merck v. Halozyme
PGR2025-00003

EX. 2400 (Merck & Co., Inc., Nov. 5, 2025 10Q SEC Filing) at 39; MTT at 8-10

“Independent” Auditor’s Statements Do Not Change What Merck & Co., Inc. Said



CONFIDENTIAL - PROTECTIVE ORDER MATERIAL

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyme Inc.,
Patent Owner.

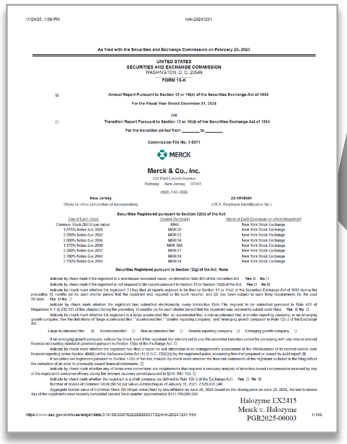
PGR2025-00003 (11,952,600 B2) PGR2025-00046 (12,091,692 B2)
PGR2025-00004 (12,018,298 B2) PGR2025-00024 (12,060,590 B2)
PGR2025-00006 (12,152,262 B2) PGR2025-00038 (12,054,758 B2)
PGR2025-00009 (12,123,035 B2) PGR2025-00052 (12,264,345 B2)
PGR2025-00017 (12,110,520 B2) PGR2025-00042 (12,037,618 B2)
PGR2025-00033 (12,049,652 B2) PGR2025-00050 (12,077,791 B2)
PGR2025-00039 (12,104,185 B2) PGR2025-00053 (12,195,773 B2)

PETITIONER’S OPPOSITION TO PATENT OWNER’S MOTION TO TERMINATE PROCEEDINGS

Opp. at 5

MSD LLC Opp. at 5

When SEC filings refer to the “Company,” they are referring to “Merck & Co., Inc. ***and its subsidiaries***.” EX2415, 131. MCI is a parent and holding company (EX1244, 2 (“Common parent corporation”)) to over 400 subsidiaries worldwide, of which MSD LLC is but one. EX1237.



As filed with the Securities and Exchange Commission on February 25, 2025

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

FORM 10-K

Merck & Co., Inc.

Halozyme EX2415
Merck v. Halozyme
PGR2025-00003

EX. 2415 at 131-132

Report of Independent Registered Public Accounting Firm

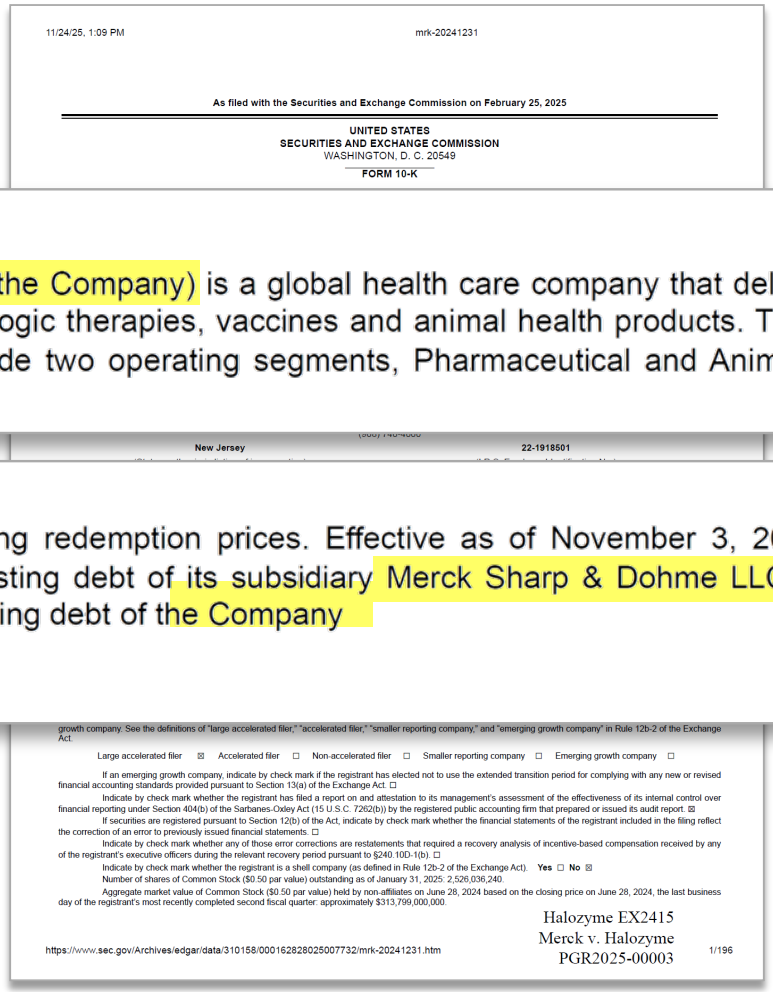
To the Board of Directors and Stockholders of Merck & Co., Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheet of Merck & Co., Inc. and its subsidiaries (the “Company”) as of December 31, 2024 and 2023, and the related consolidated statements of income, of comprehensive income (loss), of equity and of cash flows for each of the three years in the period ended December 31, 2024, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company’s internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

PricewaterhouseCoopers LLP
Florham Park, New Jersey
February 25, 2025
We have served as the Company’s auditor since 2002.

“Merck or the Company” Does Not Include MSD LLC



11/24/25, 1:09 PM mrk-20241231

As filed with the Securities and Exchange Commission on February 25, 2025

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

Item 1. Business.

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, including biologic therapies, vaccines and animal health products. The Company’s operations are principally managed on a product basis and include two operating segments, Pharmaceutical and Animal Health, both of which are reportable segments.

New Jersey 22-1918501

at Merck’s option at any time, at varying redemption prices. Effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme LLC. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company

growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Number of shares of Common Stock ($0.50 par value) outstanding as of January 31, 2025: 2,526,036,240.

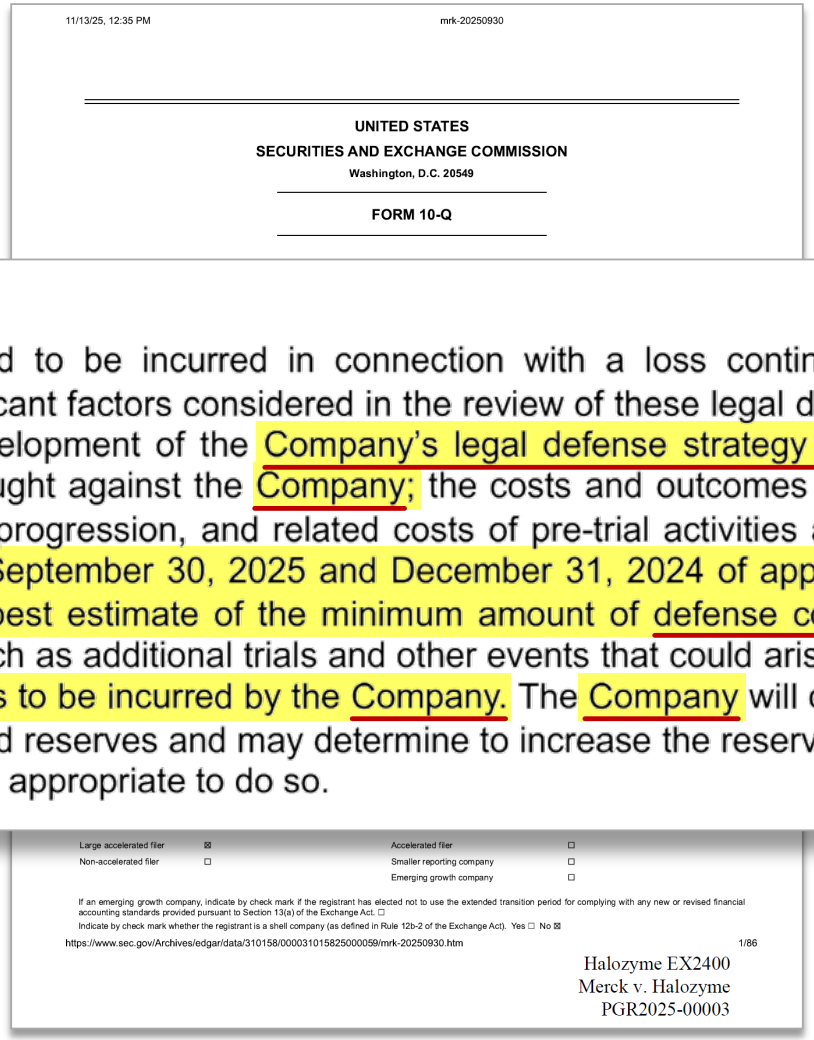
Aggregate market value of Common Stock ($0.50 par value) held by non-affiliates on June 28, 2024 based on the closing price on June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter: approximately $313,799,000,000.

Halozyme EX2415
Merck v. Halozyme
PGR2025-00003

https://www.sec.gov/Archives/edgar/data/310158/000162828025007732/mrk-20241231.htm 1/196

EX. 2415 at 4, 104-105

Merck & Co., Inc. Informed The SEC That It **Funds** The Proceedings



11/13/25, 12:35 PM mrk-20250930

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials; and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of September 30, 2025 and December 31, 2024 of approximately $220 million and $225 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

https://www.sec.gov/Archives/edgar/data/310158/000031015825000059/mrk-20250930.htm 1/86

Halozyme EX2400
Merck v. Halozyme
PGR2025-00003

EX. 2400 (Merck & Co., Inc., Nov. 5, 2025 10Q SEC Filing) at 41; MTT at 10-13

Jennifer Zachary Is Responsible For Signing Merck & Co., Inc. SEC Filings On Behalf Of Merck & Co., Inc.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MERCK & CO., INC.

Date: November 5, 2025

/s/ Jennifer Zachary
JENNIFER ZACHARY
Executive Vice President and General Counsel

Date: November 5, 2025

/s/ Dalton Smart
DALTON SMART
Senior Vice President Finance - Global Controller

EX. 2400 (Merck & Co., Inc., Nov. 5, 2025 10Q SEC Filing) at 86; MTT at 8-10

Jennifer Zachary Certifies Merck & Co., Inc. SEC Filings Are Truthful

SARBANES-OXLEY ACT OF 2002

[Public Law 107–204, Approved July 30, 2002, 116 Stat. 745]

[As Amended Through P.L. 117–328, Enacted December 29, 2022]

[Currency: This publication is a compilation of the text of Public Law 107–204. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at https://www.govinfo.gov/app/collection/comps/]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

AN ACT To protect investors by improving the accuracy and reliability of corporate disclosures made pursuant to the securities laws, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. [15 U.S.C. 7201 note] SHORT TITLE; TABLE OF CONTENTS.[1]

(a) SHORT TITLE.—This Act may be cited as the "Sarbanes-Oxley Act of 2002".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Definitions.
Sec. 3. Commission rules and enforcement.

TITLE I—PUBLIC COMPANY ACCOUNTING OVERSIGHT BOARD

Sec. 101. Establishment; administrative provisions.
Sec. 102. Registration with the Board.
Sec. 103. Auditing, quality control, and independence standards and rules.
Sec. 104. Inspections of registered public accounting firms.
Sec. 105. Investigations and disciplinary proceedings.
Sec. 106. Foreign public accounting firms.
Sec. 107. Commission oversight of the Board.
Sec. 108. Accounting standards.
Sec. 109. Funding.

TITLE II—AUDITOR INDEPENDENCE

Sec. 201. Services outside the scope of practice of auditors.
Sec. 202. Preapproval requirements.
Sec. 203. Audit partner rotation.
Sec. 204. Auditor reports to audit committees.
Sec. 205. Conforming amendments.
Sec. 206. Conflicts of interest.
Sec. 207. Study of mandatory rotation of registered public accounting firms.

[1] The Sarbanes-Oxley Act of 2002 largely amended other Acts and the amendatory provisions are not shown, however certain provisions, as amended, do appear elsewhere in this compilation.

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

TITLE III—CORPORATE RESPONSIBILITY

* * * * * * *

SEC. 302. [15 U.S.C. 7241] CORPORATE RESPONSIBILITY FOR FINANCIAL REPORTS.

(a) REGULATIONS REQUIRED.—The Commission shall, by rule, require, for each company filing periodic reports under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m, 78o(d)), that the principal executive officer or officers and the principal financial officer or officers, or persons performing similar functions, certify in each annual or quarterly report filed or submitted under either such section of such Act that—

(1) the signing officer has reviewed the report;

(2) based on the officer's knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which such statements were made, not misleading;

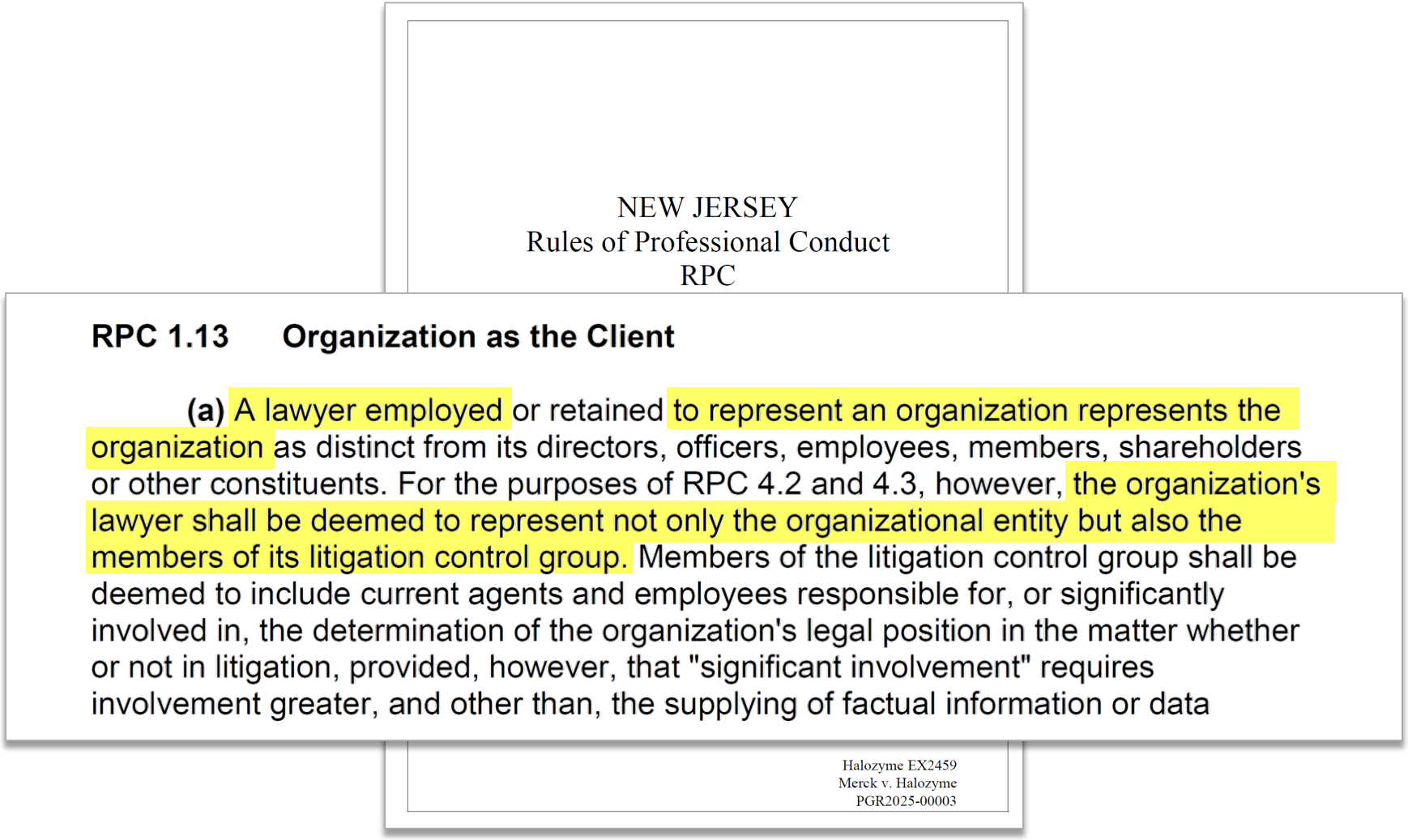
(3) based on such officer's knowledge, the financial statements, and other financial information included in the report, fairly present in all material respects the financial condition and results of operations of the issuer as of, and for, the periods presented in the report;

EX. 2457 (Sarbanes-Oxley Act 2002) at 35; MTT at 8-10



CONFIDENTIAL EX. 2403 at 8; MTT at 8-10 *CONFIDENTIAL* EX. 2402 at 8; MTT at 8-10

Ms. Zachary Has Fiduciary Duty To Her Client Merck & Co., Inc.



NEW JERSEY
Rules of Professional Conduct
RPC

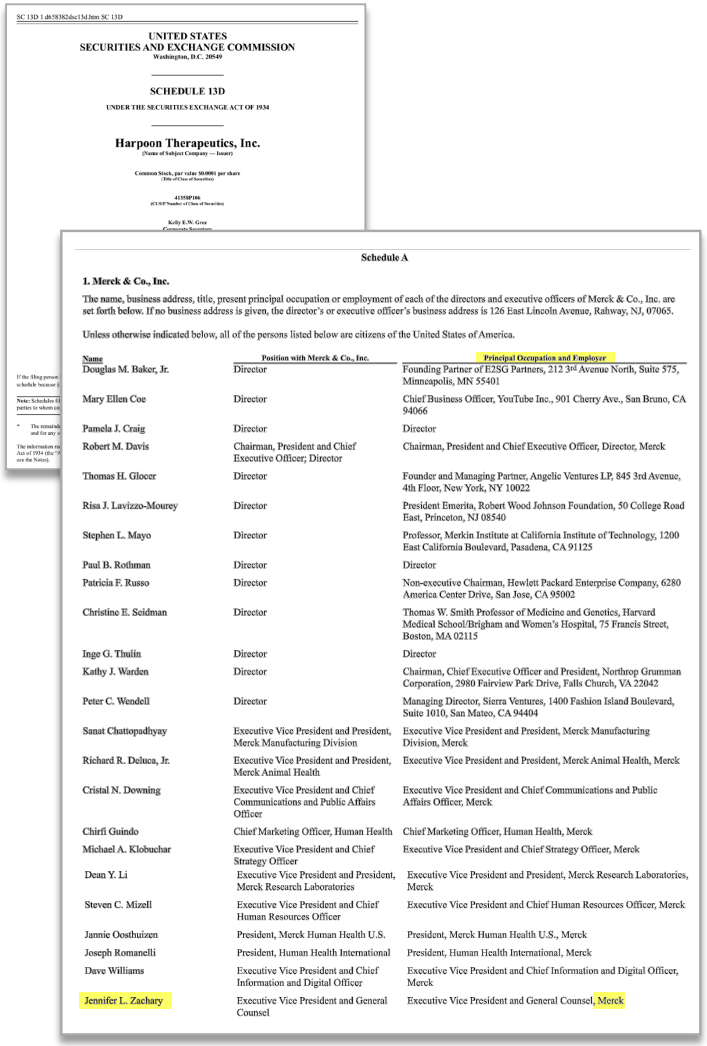
RPC 1.13 Organization as the Client

(a) A lawyer employed or retained to represent an organization represents the organization as distinct from its directors, officers, employees, members, shareholders or other constituents. For the purposes of RPC 4.2 and 4.3, however, the organization's lawyer shall be deemed to represent not only the organizational entity but also the members of its litigation control group. Members of the litigation control group shall be deemed to include current agents and employees responsible for, or significantly involved in, the determination of the organization's legal position in the matter whether or not in litigation, provided, however, that "significant involvement" requires involvement greater, and other than, the supplying of factual information or data

Halozyme EX2459
Merck v. Halozyme
PGR2025-00003

EX. 2459 at 17; MTT at 8-10

Jennifer Zachary Lists Merck & Co., Inc. For Her Principal Occupation



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 13D

UNDER THE SECURITIES EXCHANGE ACT OF 1934

Harpoon Therapeutics, Inc.

Schedule A

1. Merck & Co., Inc.

The name, business address, title, present principal occupation or employment of each of the directors and executive officers of Merck & Co., Inc. are set forth below. If no business address is given, the director's or executive officer's business address is 126 East Lincoln Avenue, Rahway, NJ, 07065.

Unless otherwise indicated below, all of the persons listed below are citizens of the United States of America.

Name	Position with Merck & Co., Inc.	Principal Occupation and Employer
Douglas M. Baker, Jr.	Director	Founding Partner of EJSG Partners, 212 3rd Avenue North, Suite 575, Minneapolis, MN 55401
Mary Ellen Coe	Director	Chief Business Officer, YouTube Inc., 901 Cherry Ave., San Bruno, CA 94066
Pamela J. Craig	Director	Director
Robert M. Davis	Chairman, President and Chief Executive Officer; Director	Chairman, President and Chief Executive Officer, Director, Merck
Thomas H. Glocer	Director	Founder and Managing Partner, Angelic Ventures LP, 845 3rd Avenue, 4th Floor, New York, NY 10022
Risa J. Lavizzo-Mourey	Director	President Emerita, Robert Wood Johnson Foundation, 50 College Road East, Princeton, NJ 08540
Stephen L. Mayo	Director	Professor, Merkin Institute at California Institute of Technology, 1200 East California Boulevard, Pasadena, CA 91125
Paul B. Rothman	Director	Director
Patricia F. Russo	Director	Non-executive Chairman, Hewlett Packard Enterprise Company, 6280 America Center Drive, San Jose, CA 95002
Christine E. Seidman	Director	Thomas W. Smith Professor of Medicine and Genetics, Harvard Medical School/Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02115
Inge G. Thulin	Director	Director
Kathy J. Warden	Director	Chairman, Chief Executive Officer and President, Northrop Grumman Corporation, 2980 Fairview Park Drive, Falls Church, VA 22042
Peter C. Wendell	Director	Managing Director, Sierra Ventures, 1400 Fashion Island Boulevard, Suite 1010, San Mateo, CA 94404
Sanat Chattopadhyay	Executive Vice President and President, Merck Manufacturing Division	Executive Vice President and President, Merck Manufacturing Division, Merck
Richard R. Deluca, Jr.	Executive Vice President and President, Merck Animal Health	Executive Vice President and President, Merck Animal Health, Merck
Cristal N. Downing	Executive Vice President and Chief Communications and Public Affairs Officer	Executive Vice President and Chief Communications and Public Affairs Officer, Merck
Chirfi Guindo	Chief Marketing Officer, Human Health	Chief Marketing Officer, Human Health, Merck
Michael A. Klobuchar	Executive Vice President and Chief Strategy Officer	Executive Vice President and Chief Strategy Officer, Merck
Dean Y. Li	Executive Vice President and President, Merck Research Laboratories	Executive Vice President and President, Merck Research Laboratories, Merck
Steven C. Mizell	Executive Vice President and Chief Human Resources Officer	Executive Vice President and Chief Human Resources Officer, Merck
Jannie Oosthuizen	President, Merck Human Health U.S.	President, Merck Human Health U.S., Merck
Joseph Romanelli	President, Human Health International	President, Human Health International, Merck
Dave Williams	Executive Vice President and Chief Information and Digital Officer	Executive Vice President and Chief Information and Digital Officer, Merck
Jennifer L. Zachary	Executive Vice President and General Counsel	Executive Vice President and General Counsel, Merck

Item 2. Identity and Background

This Schedule is being filed pursuant to Rule 13d-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), by Merck & Co., Inc., a New Jersey corporation ("Merck"), Merck Sharp & Dohme LLC, a New Jersey limited liability company ("Parent") and Hawaii Merger Sub, Inc., a Delaware corporation ("Merger Sub", and together with Merck and Parent, the "Reporting Persons"). A Joint Filing Agreement among the Reporting Persons is attached as Exhibit 99.6 hereto.

The address of the principal business and the principal office of Merck, Parent and Merger Sub is 126 East Lincoln Avenue, Rahway, NJ, 07065.

1. Merck & Co., Inc.

The name, business address, title, present principal occupation or employment of each of the directors and executive officers of Merck & Co., Inc. are set forth below. If no business address is given, the director's or executive officer's business address is 126 East Lincoln Avenue, Rahway, NJ, 07065.

Unless otherwise indicated below, all of the persons listed below are citizens of the United States of America.

Name	Position with Merck & Co., Inc.	Principal Occupation and Employer
Jennifer L. Zachary	Executive Vice President and General Counsel	Executive Vice President and General Counsel, Merck

2. Merck Sharp & Dohme LLC

The name, business address, title, present principal occupation or employment of each of the directors and executive officers of Parent are set forth below. If no business address is given, the director's or executive officer's business address is 126 East Lincoln Avenue, Rahway, NJ, 07065.

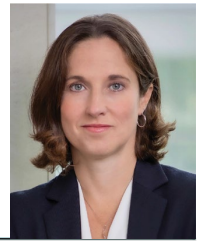
Unless otherwise indicated below, all of the persons listed below are citizens of the United States of America.

Name	Position at Parent	Principal Occupation and Employer
Jon Filderman	Manager; Vice President	Vice President, Legal, Merck
Aaron Rosenberg	Manager; Treasurer	Senior Vice President and Treasurer, Merck
Dalton Smart	Manager; President	Senior Vice President, Global Controller, Merck
Gary Henningsen, Jr.	Senior Vice President, Tax	Senior Vice President, Corporate Tax, Merck
Kelly E.W. Grez	Secretary	Assistant Vice President, Legal, Merck

EX. 2462 (MSD LLC SEC Form 13D) at 6, 12-13; MTT at 13-18

Jennifer Zachary Sets Legal Strategy For Merck & Co., Inc.

MERCK



Jennifer Zachary

Executive vice president and general counsel

Jennifer Zachary joined Merck as executive vice president and general counsel in April 2018. She serves as a legal advisor to the board of directors and company executives, leads the company's office of general counsel and sets the company's global legal strategy. She is also

Jennifer Zachary joined Merck as executive vice president and general counsel in April 2018. She serves as a legal advisor to the board of directors and company executives, leads the company's office of general counsel and sets the company's global legal strategy. She is also responsible for the company's global safety and environment, and global security functions.

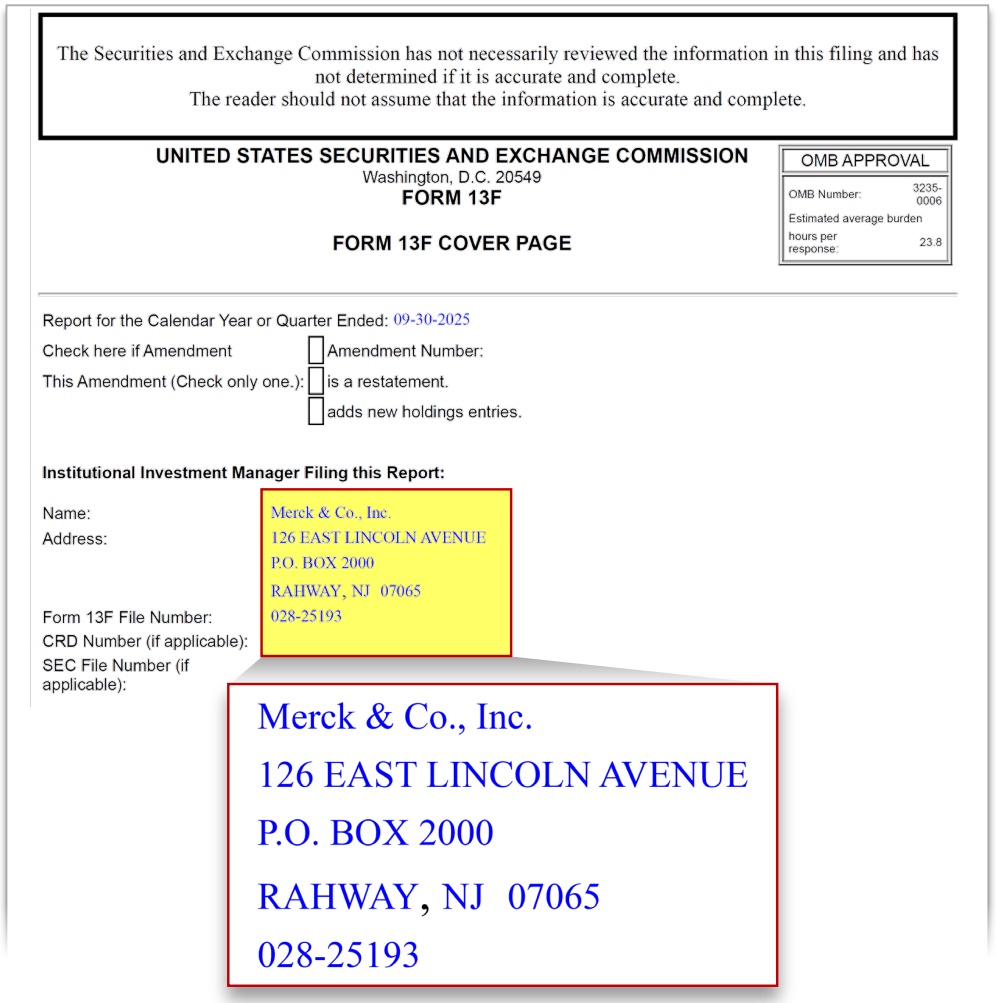
Food and Drug Administration and as a special assistant U.S. Attorney in the Civil Division of the U.S. Attorney's Office for the District of Columbia.

Jennifer serves on the board of directors for REGENXBIO Inc. and is a member of the audit committee. In addition, Jennifer is a board member of Code the Dream, a non-profit organization that teaches software development to youth from diverse, low income backgrounds.

She is a member of the bar associations for the District of Columbia, California and New Jersey. Jennifer holds a B.S. in biology and a B.A. in chemistry from Arizona State University and a J.D. from Harvard Law School.

EX. 2458 (Merck Co Bio); MTT at 13-18

Merck & Co., Inc. And Merck Sharp & Dohme LLC Have The Same Address



The Securities and Exchange Commission has not necessarily reviewed the information in this filing and has not determined if it is accurate and complete.
The reader should not assume that the information is accurate and complete.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 13F

FORM 13F COVER PAGE

OMB APPROVAL	
OMB Number:	3235-0006
Estimated average burden hours per response:	23.8

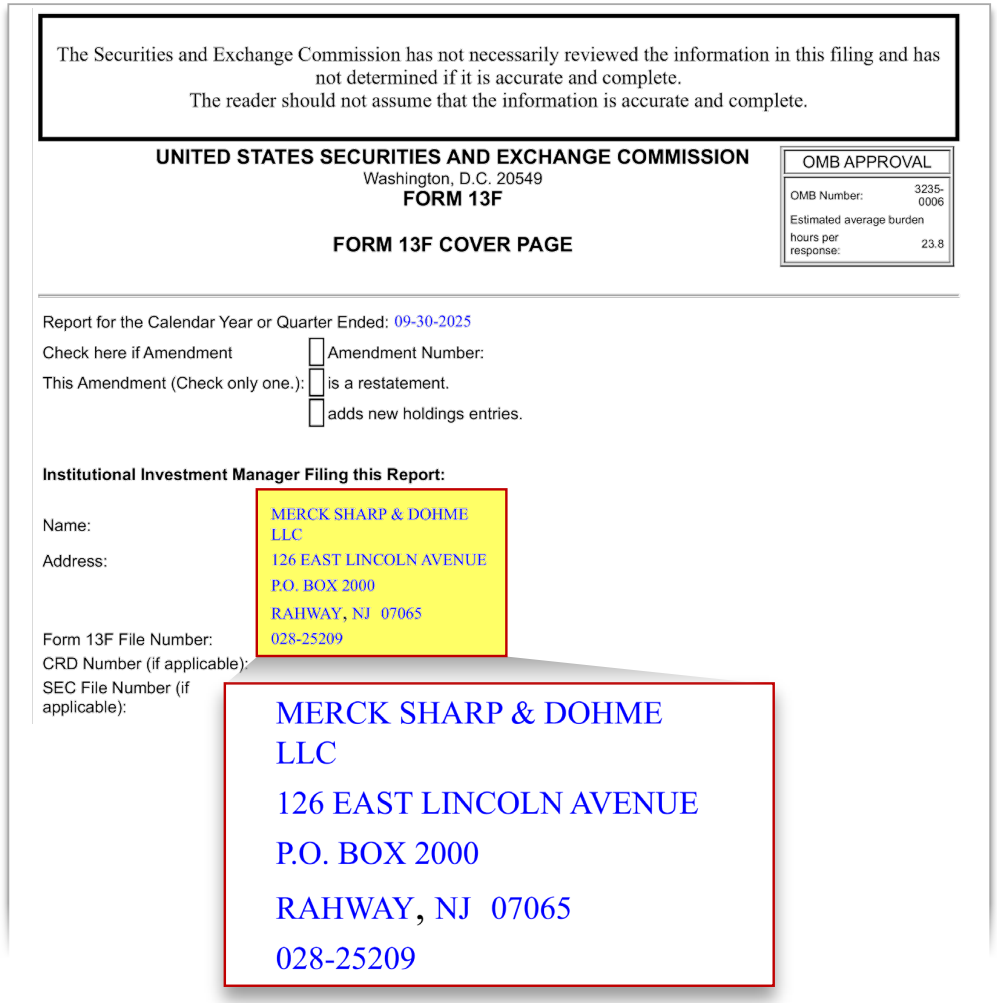
Report for the Calendar Year or Quarter Ended: 09-30-2025
Check here if Amendment ☐ Amendment Number:
This Amendment (Check only one.): ☐ is a restatement.
☐ adds new holdings entries.

Institutional Investment Manager Filing this Report:

Name: Merck & Co., Inc.
Address: 126 EAST LINCOLN AVENUE
P.O. BOX 2000
RAHWAY, NJ 07065
Form 13F File Number: 028-25193
CRD Number (if applicable):
SEC File Number (if applicable):

Merck & Co., Inc.
126 EAST LINCOLN AVENUE
P.O. BOX 2000
RAHWAY, NJ 07065
028-25193

EX. 2452 (2025-09-30 Merck Co 13F) at 1; MTT at 13-18



The Securities and Exchange Commission has not necessarily reviewed the information in this filing and has not determined if it is accurate and complete.
The reader should not assume that the information is accurate and complete.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 13F

FORM 13F COVER PAGE

OMB APPROVAL	
OMB Number:	3235-0006
Estimated average burden hours per response:	23.8

Report for the Calendar Year or Quarter Ended: 09-30-2025
Check here if Amendment ☐ Amendment Number:
This Amendment (Check only one.): ☐ is a restatement.
☐ adds new holdings entries.

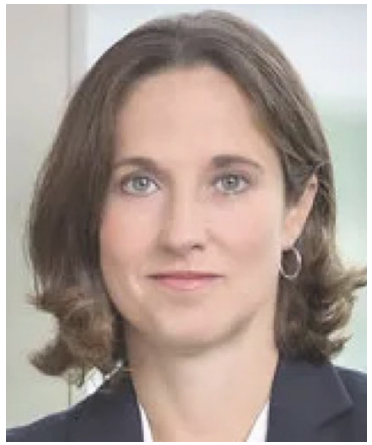
Institutional Investment Manager Filing this Report:

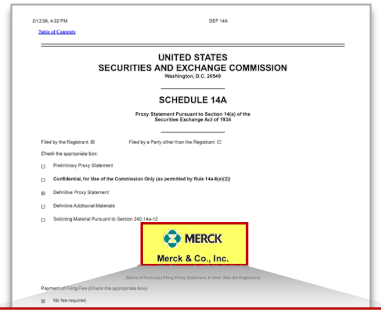
Name: MERCK SHARP & DOHME LLC
Address: 126 EAST LINCOLN AVENUE
P.O. BOX 2000
RAHWAY, NJ 07065
Form 13F File Number: 028-25209
CRD Number (if applicable):
SEC File Number (if applicable):

MERCK SHARP & DOHME LLC
126 EAST LINCOLN AVENUE
P.O. BOX 2000
RAHWAY, NJ 07065
028-25209

EX. 2453 (2025-09-30 MSD 13F) at 1; MTT at 13-18

Merck & Co., Inc. Indicates It Pays Ms. Zachary




UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

MERCK
Merck & Co., Inc.

MERCK

Merck & Co., Inc.

Pay Versus Performance Table

The following table* summarizes the SCT compensation and CAP for our CEO(s) and the average for our non-CEO NEOs for the last five fiscal years, ending December 31, 2024. In accordance with the PVP rules, the table also includes certain prescribed performance related measures.

Fiscal Year	Summary Compensation Table Total for CEO (Davis)	Summary Compensation Table Total for CEO (Frazier)	Compensation Actually Paid to CEO (Davis) (6)	Compensation Actually Paid to CEO (Frazier) (6)	Average Summary Compensation Table Total for Non-CEO NEOs	Average Compensation Actually Paid to Non-CEO NEOs (6)	Value of Initial Fixed $100 Investment Based on: Total Shareholder Return (7)	Value of Initial Fixed $100 Investment Based on: Peer Group Total Shareholder Return (8)	GAAP Net Income ($ 000's)	Non-GAAP EPS (9)
2024(1)	$23,186,064	—	$14,725,823	—	$9,487,609	$6,989,318	$133.61	$153.72	$17,117,000	$7.65
2023(2)	20,273,287	—	26,701,326	—	7,629,512	9,360,664	142.53	142.00	365,000	1.51
2022(3)	18,650,093	—	52,474,235	—	8,406,647	22,341,814	141.12	138.11	14,519,000	7.48
2021(4)	13,722,121	15,196,920	14,390,893	13,328,924	6,709,905	7,004,950	94.47	130.44	12,345,000	5.37
2020(5)	—	22,088,429	—	10,578,487	6,041,722	3,582,756	92.79	106.53	4,519,000	2.97

* Compensation shown is rounded to the nearest dollar.

(1) Non-CEO NEOs for 2024 are Ms. Litchfield, Mr. DeLuca, Ms. Larson, and Dr. Li.

(2) Non-CEO NEOs for 2023 are Ms. Litchfield, Mr. Chattopadhyay, Mr. DeLuca, and Dr. Li.

(3) Non-CEO NEOs for 2022 are Mr. Frazier, Ms. Litchfield, Mr. Guindo, Dr. Li, and Ms. Zachary. Since ly his compensation is shown in the CEO SCT and CAP columns.

(4) Non-CEO NEOs for 2021 are Ms. Litchfield, Mr. Clyburn, Mr. DeLuca, and Dr. Li. As a result of Mr. Frazier's retirement as CEO, effective June 30, 2021, and Mr. Davis's promotion to CEO, effective July 1, 2021, the Pay versus Performance table includes the CEO in 2021. The SCT and CAP amounts reported for Mr. Davis and Mr. Frazier reflect compensation for all of 2021, not just e CEO.

(5) Non-CEO NEOs for 2020 are Mr. Davis, Mr. Chattopadhyay, Dr. Perlmutter, and Ms. Zachary. Since nly his compensation is shown in the CEO SCT and CAP columns.

(6) See the table on page 67 for additional details on the calculation of the CAP value.

(7) TSR assumes an initial $100 investment in Company stock beginning on December 31, 2019. TSR is cumulative, with the value determined at the end of each applicable fiscal year, calculated in accordance with Item 201(e) of Regulation S-K.

(8) Peer Group TSR assumes an initial $100 investment in the Company's primary peer group (market cap-weighted). As described on page 47, the Company's primary peer group consists of the following companies: AbbVie, Amgen, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, Gilead Sciences, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, Roche Holding AG, and Sanofi.

(9) The SEC requires the disclosure of a company selected measure, representing the most important financial metric used for determining CAP for the current fiscal year. As described in more detail on page 69, the selected measure for 2024 is non-GAAP EPS. Refer to Appendix A on page 100 for a reconciliation between GAAP and non-GAAP financial measures. Appendix B on page 102 provides an explanation of adjustments to non-GAAP results for incentive plans purposes.

Ms. Zachary

Ms. Zachary

EX. 2463 (2025 Proxy meeting - DEF 14A) at 66; MTT at 13-18

Petitioner's Backup Counsel – Mark Stewart

Paper No. 1

Filed: November 12, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyme Inc.,
Patent Owner.

Case No. PGR2025-00003
U.S. Patent No. 11,952,600

PETITION FOR POST GRANT REVIEW

PGR2025-00003 Petition at 1; MTT at 13-18

3. Counsel and Service Information

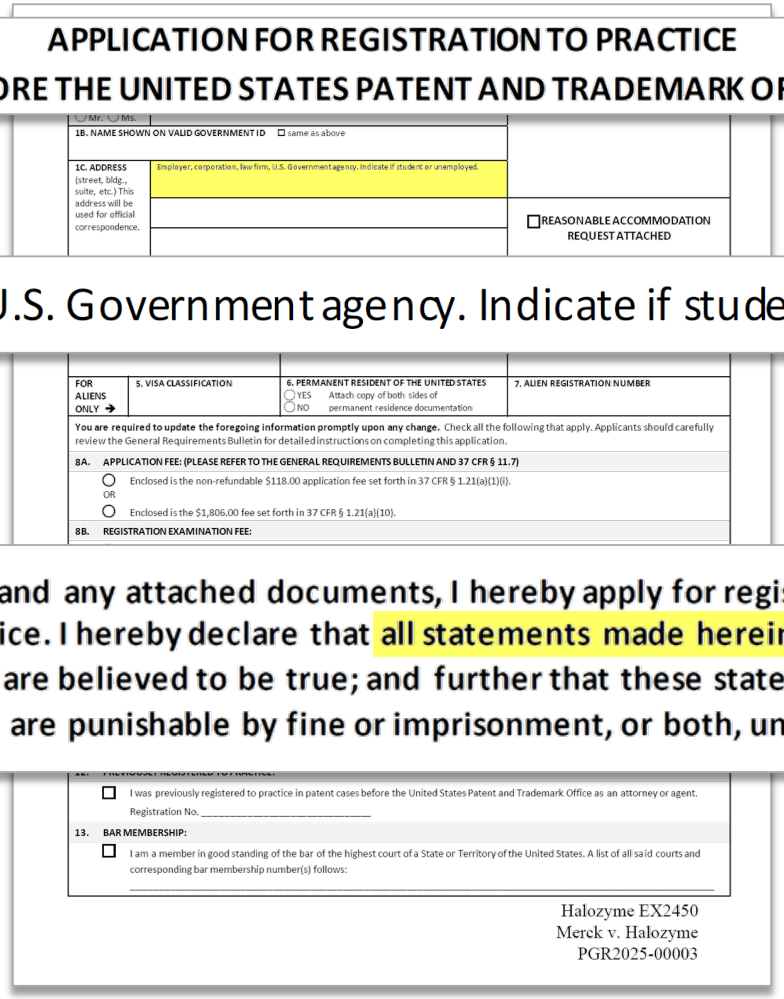
Lead Counsel	Backup Counsel	Backup Counsel
Jeffrey P. Kushan	Leif Peterson	Mark Stewart
Reg. No. 43,401	*Pro Hac Vice* forthcoming	Reg. No. 43,936
Sidley Austin LLP	Sidley Austin LLP	Merck Sharp & Dohme LLC
1501 K Street, N.W.	1 S Dearborn Street	126 E. Lincoln Ave.
Washington, D.C. 20005	Chicago, IL 60603	Rahway, New Jersey 07065
jkushan@sidley.com	leif.peterson@sidley.com	Mark.stewart@merck.com
(202) 736-8914	(312) 853-7190	(732) 594-6302

Backup Counsel
Mark Stewart
Reg. No. 43,936
Merck Sharp & Dohme LLC
126 E. Lincoln Ave.
Rahway, New Jersey 07065
Mark.stewart@merck.com
(732) 594-6302

PGR2025-00003 Petition at 7; MTT at 13-18

Mark Stewart Serves Merck & Co., Inc.

APPLICATION FOR REGISTRATION TO PRACTICE
BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE



1B. NAME SHOWN ON VALID GOVERNMENT ID ☐ same as above

1C. ADDRESS (street, bldg., suite, etc.) This address will be used for official correspondence.

Employer, corporation, law firm, U.S. Government agency. Indicate if student or unemployed.

☐ REASONABLE ACCOMMODATION REQUEST ATTACHED

FOR ALIENS ONLY → | 5. VISA CLASSIFICATION | 6. PERMANENT RESIDENT OF THE UNITED STATES ○ YES ○ NO Attach copy of both sides of permanent residence documentation | 7. ALIEN REGISTRATION NUMBER

You are required to update the foregoing information promptly upon any change. Check all the following that apply. Applicants should carefully review the General Requirements Bulletin for detailed instructions on completing this application.

8A. APPLICATION FEE: (PLEASE REFER TO THE GENERAL REQUIREMENTS BULLETIN AND 37 CFR § 11.7)

○ Enclosed is the non-refundable $118.00 application fee set forth in 37 CFR § 1.21(a)(1)(i).

OR

○ Enclosed is the $1,806.00 fee set forth in 37 CFR § 1.21(a)(10).

8B. REGISTRATION EXAMINATION FEE:

Upon the basis of the foregoing information and any attached documents, I hereby apply for registration to practice in patent matters before the United States Patent and Trademark Office. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001.

☐ I was previously registered to practice in patent cases before the United States Patent and Trademark Office as an attorney or agent.
Registration No. _____

13. BAR MEMBERSHIP:

☐ I am a member in good standing of the bar of the highest court of a State or Territory of the United States. A list of all said courts and corresponding bar membership number(s) follows:

_____

Halozyme EX2450
Merck v. Halozyme
PGR2025-00003

EX. 2450 (OED PTO Form 158) at 1, 2; MTT at 13-18

Mark Stewart Serves Merck & Co., Inc.

Practitioner Search Results

Last Name	First Name	Middle Name	Phone Number	City	State/Province	Postal Code	Status	Accepting New Clients
Stewart	Mark	J	(317) 370-6029	Rahway	NJ	07065	Patent Attorney	YES

Suffix

Firm Name
Merck Sharp & Dohme, LLC Merck and Co.

Address
126 E. Lincoln Ave

Country
UNITED STATES

Registration Number
43,936

Status
Patent Attorney

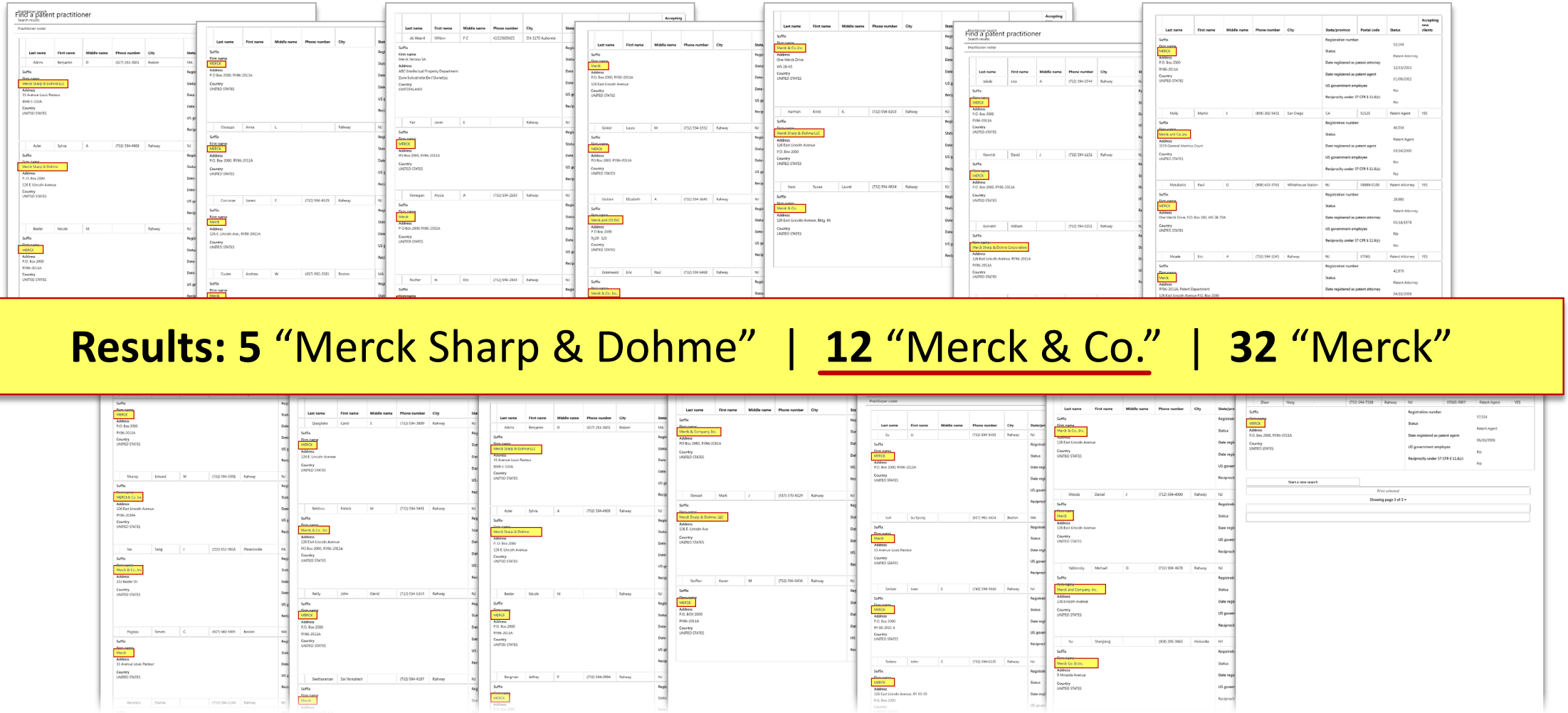
Date registered as patent attorney
04/05/2000

Date registered as patent agent
02/16/1999

US Government Employee
No

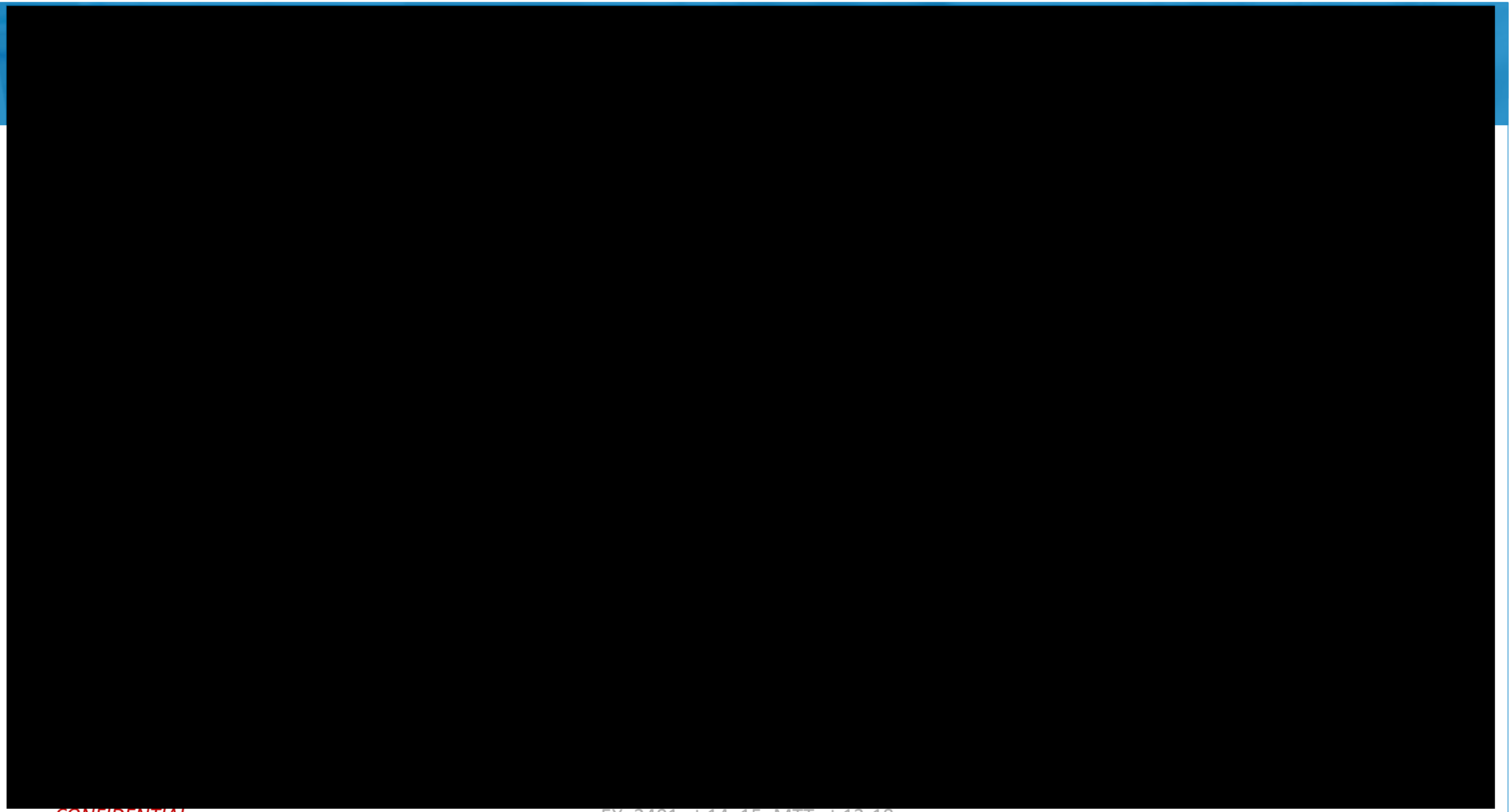
EX. 2416 at 1; MTT at 13-18

Corporate Lines Are Blurred To Insiders Of Merck Sharp & Dohme LLC And Merck & Co., Inc.



Results: 5 “Merck Sharp & Dohme” | **12** “Merck & Co.” | **32** “Merck”

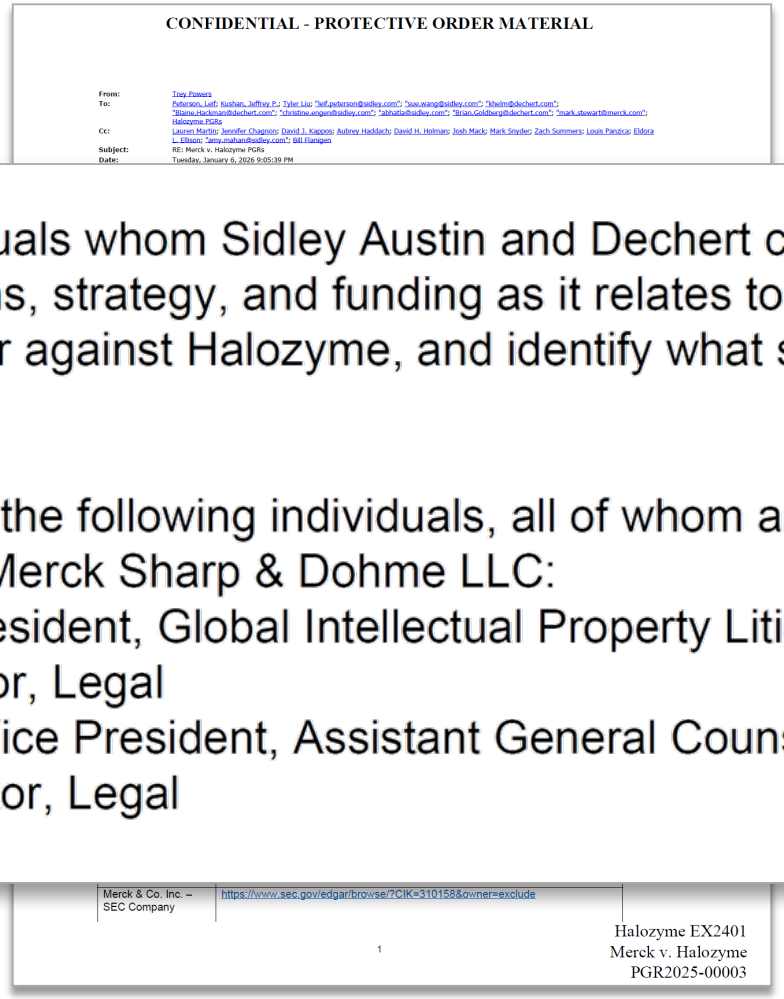
EX. 2465 (OED Practitioner Search - Merck & Co); MTT at 13-18



CONFIDENTIAL

EX. 2401 at 14, 15; MTT at 13-18

Petitioner Identified Individuals That, Themselves, Represent They Serve Merck & Co., Inc.



CONFIDENTIAL - PROTECTIVE ORDER MATERIAL

From: Trey Powers
To: Peterson, Leif; Kushan, Jeffrey P.; Tyler Liu; "leif.peterson@sidley.com"; "sue.wang@sidley.com"; "khelm@dechert.com"; "Blaine.Hackman@dechert.com"; "christine.angen@sidley.com"; "abhatia@sidley.com"; "Brian.Goldberg@dechert.com"; "mark.stewart@merck.com"; Halozyme PGRs
Cc: Lauren Martin; Jennifer Chagnon; David J. Kappos; Aubrey Haddach; David H. Holmes; Josh Mack; Mark Snyder; Zach Summers; Louis Panzica; Eldora L. Ellison; "amy.mahan@sidley.com"; Bill Flanigen
Subject: RE: Merck v. Halozyme PGRs
Date: Tuesday, January 6, 2026 9:05:39 PM

6. Identify all individuals whom Sidley Austin and Dechert contact or have contacted regarding instructions, strategy, and funding as it relates to any of the 14 PGR proceedings brought by Petitioner against Halozyme, and identify what specific entity employs each of them.

Response: Petitioner identifies the following individuals, all of whom are employed by and hold titles within the legal department of Merck Sharp & Dohme LLC:

- Mark Stewart, Vice President, Global Intellectual Property Litigation
- Eric Majchrzak, Director, Legal
- Laura Ginkel, Senior Vice President, Assistant General Counsel
- Li Su, Director – Director, Legal

Merck & Co. Inc. – SEC Company | https://www.sec.gov/edgar/browse/?CIK=310158&owner=exclude

1

Halozyme EX2401
Merck v. Halozyme
PGR2025-00003

EX. 2401 at 9; MTT at 13-18

CONFIDENTIAL

Laura Ginkel – Joined A Supreme Court Brief On Behalf Of Merck & Co., Inc.

No. 22-148

IN THE

Supreme Court of the United States

JACK DANIEL'S PROPERTIES, INC.,

Petitioner,

v.

VIP PRODUCTS LLC,

Respondent.

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

BRIEF OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

KAREN COCHRAN ERIC R. MORAN

2a

Appendix

Gary C. Ganzi
Evoqua Water Technologies, LLC

Tanuja Garde
The Boeing Co.

Robert Giles
Qualcomm Inc.

Laura Ginkel
Merck & Co.

Krish Gupta
Dell Technologies

William Miller
General Mills, Inc.

Kelsey L. Milman
Caterpillar Inc.

Jeffrey Myers
Apple Inc.

Robin Nava
Schlumberger, Ltd.

Christina Petersson
Ericsson

EX. 2446 (Amicus Curiae Brief at 1, Appx 2a (pdf pg 22)); MTT at 13-18

Laura Ginkel – Holds Herself Out As Serving "Merck"

Last name	First name	Middle name	Phone number	City	State/province	Postal code	Status	Accepting new clients
Ginkel	Laura	M	(732) 594-1932	Rahway	NJ	07065-0907	Patent Agent	YES

Suffix

Firm name
MERCK

Address
PO Box 2000, RY86-2011A

Country
UNITED STATES

Registration number
51,737

Status
Patent Agent

Date registered as patent agent
08/05/2002

US government employee
No

Reciprocity under 37 CFR § 11.6(c)
No

EX. 2465 (Merck OED Search Results) at 4; MTT at 13-18

Laura Ginkel – IPO Association States She Serves Merck & Co., Inc.

Intellectual® Property Owners Association

MEMBERS

David Alban
Xylem

Scott Barker
Micron Technology, Inc.

Dan Choi
Microsoft Corporation

Brandon Clark
SLB

Ewa Davison
The Boeing Co.

Jake Feldman
Kenvue

Mony Ghose
Danaher Corporation

Krish Gupta
Dell Technologies

Scott Hayden
Amazon.Com

Thomas R. Kingsbury
Bridgestone Americas, Inc.

Matthew Anderson
Medtronic, Inc.

Thomas R. Beall
Corning Incorporated

Robinson Clark
Exxon Mobil Corp.

Tonya Combs
Eli Lilly and Co.

Anthony DiBartolomeo
SAP SE

Louis Foreman
Enventys

Robert Giles
Qualcomm Incorporated

Henry Hadad
Bristol Myers Squibb Company

Emily Johnson
Amgen, Inc.

Laurie Kowalsky
Koninklijke Philips N.V.

Ronald A. Antush
Nokia of Americas Corp

Tyrome Y. Brown
Dolby Laboratories

Scott Clark
InterDigital

Jamie Davis
Bayer Intellectual Property GmbH

Cass Dottridge
Cargill, Incorporated

Darryl P. Frickey
Dow Chemical Co.

Laura M. Ginkel
Merck & Co Inc.

Aamir Haq
Hewlett Packard Enterprise

Michael King
Caterpillar Inc.

Christine Lam
NetApp

Laura M. Ginkel
Merck & Co Inc.

EX. 2447 (IPO Board of Directors - Intellectual Property Owners Association); MTT at 13-18

Laura Ginkel – IPO Association States She Serves Merck & Co., Inc.

ChIPs ADVANCING WOMEN TECH · LAW · POLICY

Full Name

Laura Ginkel



Job Title

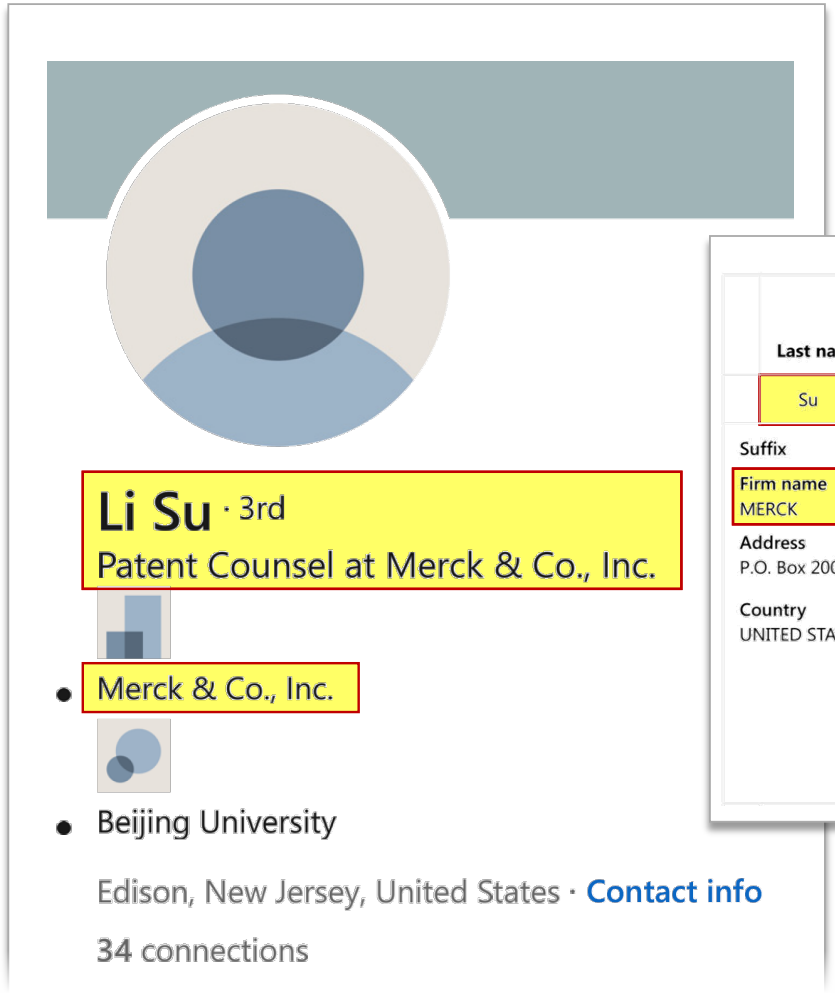
AVP & Group Managing Counsel

Speaker Bio

Laura is an Associate Vice President & Group Managing Counsel in the Intellectual Property Group of Merck & Co., Inc. Her team manages the procurement of patents in support of Merck's human health R&D efforts and product development. She is a graduate of Fordham University Law School, which she attended after receiving her Ph.D. in Cellular and Molecular Biology from the University of Washington. Laura started at Merck as an intern in the Intellectual Property Group while in law school and has been with the company for 18 years. She supported both small and large molecule (biologics and vaccines) programs prior to becoming a manager in the group and spent almost three years in Merck's Corporate Transactions Legal group supporting M&A and various collaboration projects.

EX. 2448 (Speaker Details - 2020 ChIPs Global Summit); MTT at 13-18

Li Su – Patent Counsel At Merck & Co., Inc.



Last name	First name	Middle name	Phone number	City	State/province	Postal code	Status	Accepting new clients
Su	Li		(732) 594-5455	Rahway	NJ	07065-0907	Patent Attorney	YES

Suffix

Firm name
MERCK

Address
P.O. Box 2000, RY86-2011A

Country
UNITED STATES

Registration number
45,141

Status
Patent Attorney

Date registered as patent attorney
12/28/2004

Date registered as patent agent
09/08/1999

US government employee
No

Reciprocity under 37 CFR § 11.6(c)
No

EX. 2449 (Li Su – LinkedIn) at 1; MTT at 13-18

EX. 2465 (Li Su - USPTO patent pratitioner search) at 11; MTT at 13-18

Merck & Co., Inc. Generates Revenue From Sales Of KEYTRUDA Qlex™

EX-99.1 2 tm264564d1_ex99-1.htm EXHIBIT 99.1

Exhibit 99.1



News Release

Merck & Co., Inc., Rahway, N.J., USA Announces Fourth-Quarter and Full-Year 2025 Financial Results; Highlights Progress Advancing Broad, Diverse Pipeline

Reports Strength in Oncology and Animal Health, Plus Increasing Contributions From WINREVAIR and CAPVAXIVE

- Fourth-Quarter Worldwide Sales Were $16.4 Billion (5% Growth; 4% Growth ex-FX)
- Fourth-Quarter GAAP EPS Was $1.19; Non-GAAP EPS Was $2.04; GAAP and Non-GAAP EPS Include a Charge of $0.05 per Share for the Acquisition of MK-8690 Sole Global Rights
- Full-Year Worldwide Sales Were $65.0 Billion (1% Growth; 2% Growth ex-FX)
    - o KEYTRUDA/KEYTRUDA QLEX Sales Were $31.7 Billion (7% Growth Both Nominally and ex-FX); Includes KEYTRUDA QLEX Sales of $40 Million

EX. 2467 (Merck Co From 8K ex99.1) at 1; MTT at 13-18

Merck & Co., Inc. Has A Financial Interest In The Outcome Of These Proceedings

MERCK & CO., INC., RAHWAY, N.J., USA
FRANCHISE / KEY PRODUCT SALES
FOURTH QUARTER 2025
(AMOUNTS IN MILLIONS)
(UNAUDITED)
Table 3a

	Global			U.S.			International		
	4Q 2025	4Q 2024	% Change	4Q 2025	4Q 2024	% Change	4Q 2025	4Q 2024	% Change
TOTAL SALES [1]	$ 16,400	$ 15,624	5	$ 9,139	$ 8,188	12	$ 7,261	$ 7,436	-2
PHARMACEUTICAL	14,843	14,042	6	8,662	7,728	12	6,181	6,314	-2
Oncology									
Keytruda	8,337	7,836	6	4,892	4,841	1	3,445	2,996	15
Keytruda Qlex	35		-	33		-	2		-

Keytruda Qlex

EX. 2468 (Merck Co From 8K ex99.2) at 4; MTT at 13-18

Merck & Co., Inc. Is The Licensee And Pays Royalties For KEYTRUDA Qlex™

Merck & Co., Inc. (Merck or the Company)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

In February 2024, Merck and Alteogen Inc. (Alteogen) converted their existing non-exclusive license agreement into an exclusive license for the use of Alteogen's proprietary berahyaluronidase alfa for the formulation of subcutaneous pembrolizumab. Pursuant to the amended agreement, Alteogen is eligible to receive regulatory approval milestone payments of up to $51 million, as well as annual and cumulative sales-based milestone payments of up to $1.0 billion in the aggregate. After the achievement of all sales-based milestones, a 2% royalty on net sales is payable to Alteogen. In September 2025, the U.S. Food and Drug Administration (FDA) approved *Keytruda Qlex* (pembrolizumab and berahyaluronidase alfa-pmph) injection, which triggered regulatory milestone payments of $25 million in the aggregate from Merck to Alteogen. Additionally, following FDA approval, the Company determined that it was probable that sales of *Keytruda Qlex* in the future would trigger $680 million of sales-based milestone payments from Merck to Alteogen. Accordingly, in the third quarter of 2025, Merck recorded a $705 million liability for these regulatory and sales-based milestone payments and a corresponding intangible asset related to *Keytruda Qlex* included in *Other Intangibles, Net.* The intangible asset will be amortized over its estimated useful life through December 2030. The $25 million of regulatory milestone payments were made in October 2025; the future sales-based milestone payments will be paid upon achievement of the corresponding milestone.

3.700% Notes due 2044 MRK/44 New York Stock Exchange

The Company is a party to license agreements pursuant to which the Company pays royalties on net sales of *Keytruda*. Under the terms of the more significant of these agreements, Merck pays a royalty of 2.5% on worldwide net sales of *Keytruda*; this royalty expires on December 31, 2026. The Company pays an additional 2% royalty on worldwide net sales of *Keytruda* to another third party, the termination date of which varies by country; this royalty expired in the U.S. in September 2024 and expired in several major European markets in the third quarter of 2025, with the royalty set to expire in the remaining major European markets in the fourth quarter of 2025. The royalty expenses are included in *Cost of sales*.

Halozyme EX2400
Merck v. Halozyme
PGR2025-00003

EX. 2400 (Merck & Co., Inc., Nov. 5, 2025 10Q SEC Filing) at 6, 8, 61

In Previous Proceedings Involving KEYTRUDA®, MSD Listed Merck & Co., Inc. As An RPI

Merck Sharp & Dohme LLC v. The Johns Hopkins University, IPR2024-00240 (P.T.A.B.), November 30, 2023
Merck Sharp & Dohme LLC v. The Johns Hopkins University, IPR2024-00622 (P.T.A.B.), March 4, 2024
Merck Sharp & Dohme LLC v. The Johns Hopkins University, IPR2024-00623 (P.T.A.B.), March 4, 2024
Merck Sharp & Dohme LLC v. The Johns Hopkins University, IPR2024-00624 (P.T.A.B.), March 4, 2024
Merck Sharp & Dohme LLC v. The Johns Hopkins University, IPR2024-00625 (P.T.A.B.), March 4, 2024
Merck Sharp & Dohme LLC v. The Johns Hopkins University, IPR2024-00647 (P.T.A.B.), March 13, 2024
Merck Sharp & Dohme LLC v. The Johns Hopkins University, IPR2024-00648 (P.T.A.B.), March 13, 2024
Merck Sharp & Dohme LLC v. The Johns Hopkins University, IPR2024-00649 (P.T.A.B.), March 13, 2024
Merck Sharp & Dohme LLC v. The Johns Hopkins University, IPR2024-00650 (P.T.A.B.), March 13, 2024

VIII. MANDATORY NOTICES UNDER 37 CFR § 42.8

Real Parties-in-Interest: Pursuant to 37 C.F.R. § 42.8(b)(1), Merck identifies Merck Sharp & Dohme LLC and Merck & Co., Inc. as the real parties-in-interest.

Related Matters: Pursuant to 37 C.F.R. § 42.8(b)(2), Merck identifies the related matters. The '356 patent is at issue in the following pending litigation: *Merck Sharp & Dohme LLC v. The Johns Hopkins University*, 1:22-cv-03059-JRR (D. Md.). Additionally, a petition for U.S. Patent No. 11,591,393,

Merck & Co., Inc.

EX. 2417 at 67, *See* EX. 2418-2425; MTT at 13-18

In Previous Proceedings Involving KEYTRUDA®, MSD Listed Merck & Co., Inc. As An RPI

Merck Sharp & Dohme Corp. v. Ono Pharm. Co., Ltd., IPR2016-01221, Paper 1 at i-ii (P.T.A.B. June 29, 2016)
Merck Sharp & Dohme Corp. v. Ono Pharm. Co., Ltd., IPR2016-01218, Paper 1 at i-ii (P.T.A.B. June 29, 2016)
Merck Sharp & Dohme Corp. v. Ono Pharm. Co., Ltd., IPR2016-01217, Paper 1 at i-ii (P.T.A.B. June 29, 2016)
Merck Sharp & Dohme Corp. v. Ono Pharm. Co., Ltd., IPR2016-01219, Paper 1 at i-ii (P.T.A.B. June 30, 2016)

II. Mandatory Notices (37 CFR § 42.8(b))

A. Real Party in Interest (§ 42.8(b)(1))

Merck Sharp & Dohme Corp. and Merck & Co., Inc (Merck) are the real parties of interest of this petition. No other entity is a real party of interest or a

his petition.

Merck & Co., Inc

Lead Counsel
Jeffrey P. Kushan
Reg. No. 43,401
jkushan@sidley.com
(202) 736-8914

MTT at 16

Summary of Evidence

Control	Blurred Lines	Specific Benefit
SEC statements attributing filing to Merck & Co. Opp., 9; EX. 2400, 6, 53; EX. 2454, 22; EX. 2415, 25, 75, 104-105; EX. 1234, 4; MTT 2.	Evidence of Control EX. 2409; EX. 2410; EX. 2411; EX. 2412; EX. 2452; EX. 2453; MTT, 15.	Merck & Co. sells KEYTRUDA Qlex™ Opp., 22; MTT, 2, 18-19
Funding by Merck & Co. MTT, 15; EX. 2463, 66; Opp. 14; EX. 2452; EX. 2453; EX. 2464.	Four people directly involved in "instructions, strategy, and funding" these PGRs MTT, 14-16; EX. 2446, Appendix 2a; EX. 2447; EX. 2488; EX2449, EX 2416; Opp., 21.	Merck & Co. pays royalties for patents covering KEYTRUDA Qlex™ MTT, 10-11, 18, EX. 2400 at 8, 21, 25
Zachary works for Merck & Co. (principal occupation) MTT, 53; EX. 2400 at 53; EX. 2462 at 6, 12-13	Employee Representations regarding employment MTT, 14-16; EX. 2446, Appendix 2a; EX. 2447; EX. 2488; EX. 2449, EX. 2416	Merck & Co. purchased Inventories for KEYTRUDA Qlex™ launch EX. 2400 at 8; EX. 2454 at 18
[redacted] EX. 2402 at 8; EX. 2403 at 8; MTT, 2; Opp., 9-10	Overlapping executives including Ms. Zachary – General Counsel EX. 2407; EX 2408; EX. 2400 at 53; EX. 2462 at 12-13; EX. 2463 at 66; MTT, 14-15.	Merck & Co. admitted litigation risk to KEYTRUDA Qlex™ MTT, 18-19, 22; EX. 2400 at 25, 21
Zachary sets Merck & Co.'s "global legal strategy." MTT, 10; Opp., 11; EX. 2458	Merck & Co. listed as RPI in KEYTRUDA® IPRs MTT, 16. *See, e.g.*, EX. 2417–EX. 2425.	

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Halozyme Timely Raised The RPI Issue

OCT 28, 2025

Corning designated as precedential

Halozyme begins investigating whether Petitioner identified all RPIs

NOV 5, 2025

Merck & Co., Inc. files its SEC Form 10-Q
EX. 2400

Halozyme continues investigating the RPI issue

NOV 11, 2025

Halozyme contacts opposing counsel requesting additional discovery regarding the RPI issue

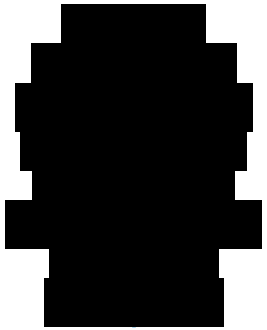
Halozyme continues to pursue additional discovery

DEC 23, 2025

The Board authorizes Halozyme's motion for additional discovery

DEC 29, 2025

Petitioner responds to Halozyme's initial discovery requests



JAN 6, 2026

Halozyme files motion for additional discovery

FEB 16, 2026

Halozyme files its motion to terminate

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See EX. 2401; MTT at 19-20

Thank You

quinn emanuel
quinn emanuel urquhart & sullivan, llp

Halozyme

Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX