

PGR2025-00003 – U.S. Patent No. 11,952,600 B2
PGR2025-00004 – U.S. Patent No. 12,018,298 B2
PGR2025-00006 – U.S. Patent No. 12,152,262 B2
PGR2025-00009 – U.S. Patent No. 12,123,035 B2

Merck Sharp & Dohme, LLC

Demonstratives Opposing

Patent Owner's Motion to Terminate

CONFIDENTIAL – PROTECTIVE ORDER MATERIAL

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Overview

- Petitioner Merck Sharp & Dohme, LLC (“MSD LLC” or “Petitioner”) has been the sole party controlling and funding the PGR proceedings
 - MSD LLC’s in-house counsel has directed and overseen the PGR petitions
 - Halozyme’s speculative theory that Petitioner’s corporate parent, Merck and Co., Inc. (“MCI”), is an RPI is rebutted by the record evidence
- MSD LLC and MCI have maintained corporate separateness
- MCI receives only a generalized benefit from this proceeding via success of its subsidiary
- Halozyme waived its RPI argument due to lack of action even after *Corning* was designated precedential

Petitioner Voluntarily Supplied Halozyme with All Requested Evidence

- In December 2025, Petitioner voluntarily and completely responded to Halozyme's discovery request, including:
 - Answering Halozyme's interrogatories
 - Producing official employment records, corporate registrations, engagement letters, billing records, and pertinent facts about the corporate structure of MSD LLC and MCI.
- The Board found the redacted information “does not ‘reveal blurred corporate lines between MSD and [MCI]’ or ‘the ability of [MCI] to control and fund’ these PGR proceedings.” PGR2025-00003, Paper 77 at 3-4; Paper 80 at 3.
- Halozyme's motion and reply rely largely ignore this evidence.

MSD LLC Alone Controls the PGRs

MSD LLC Positions	Exhibits
Mark Stewart, Vice President, Global Intellectual Property Litigation	EX2404; EX2430; EX2434
Eric Majchrzak, Director, Legal	EX2433
Laura Ginkel, Senior Vice President, Assistant General Counsel	EX2434; EX2431
Li Su, Director, Legal	EX2345

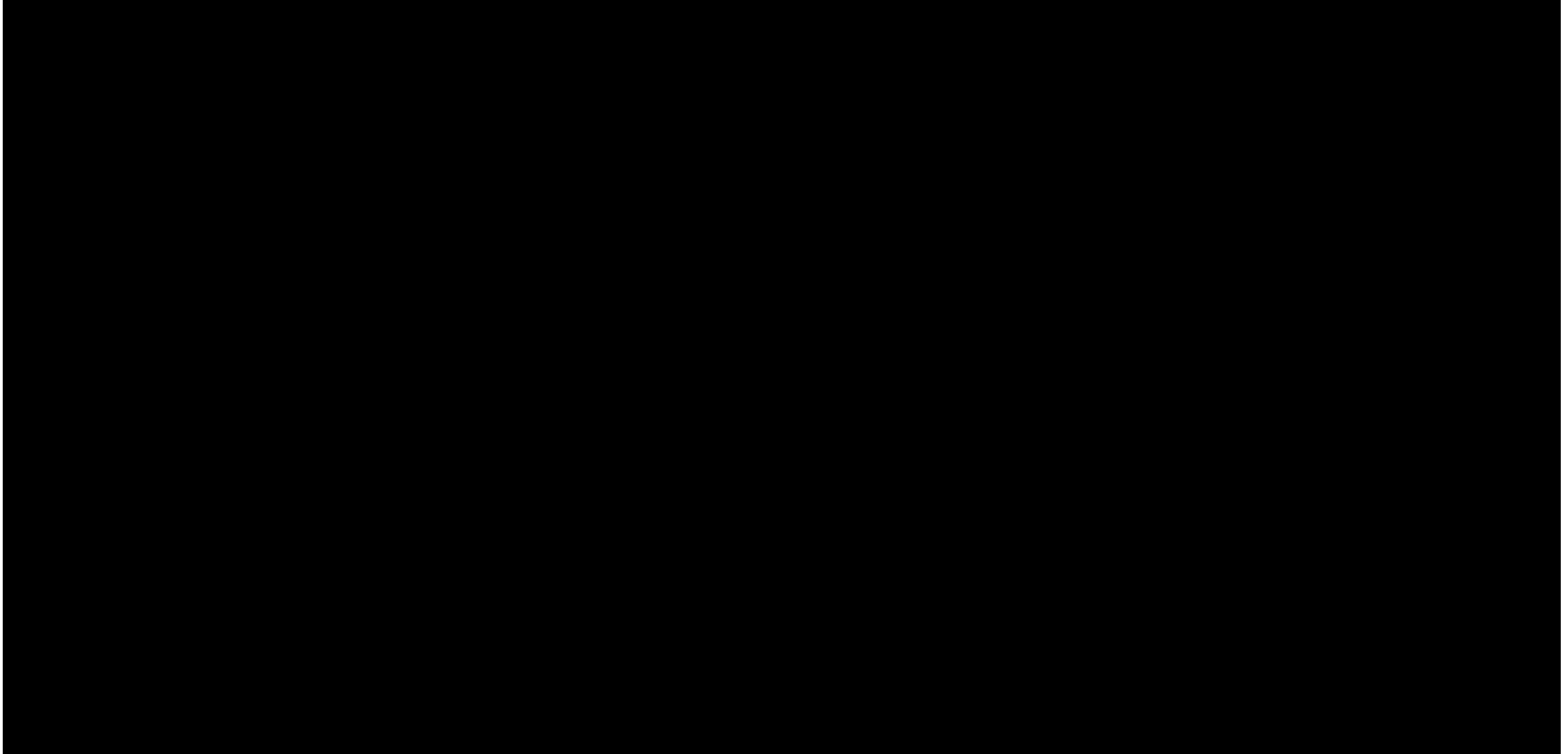
Opp. at 8-9; EX2401

CONFIDENTIAL – PROTECTIVE ORDER MATERIAL

Opp. at 13; EX2405; EX2406

CONFIDENTIAL – PROTECTIVE ORDER MATERIAL

MSD LLC Alone Funds the PGRs

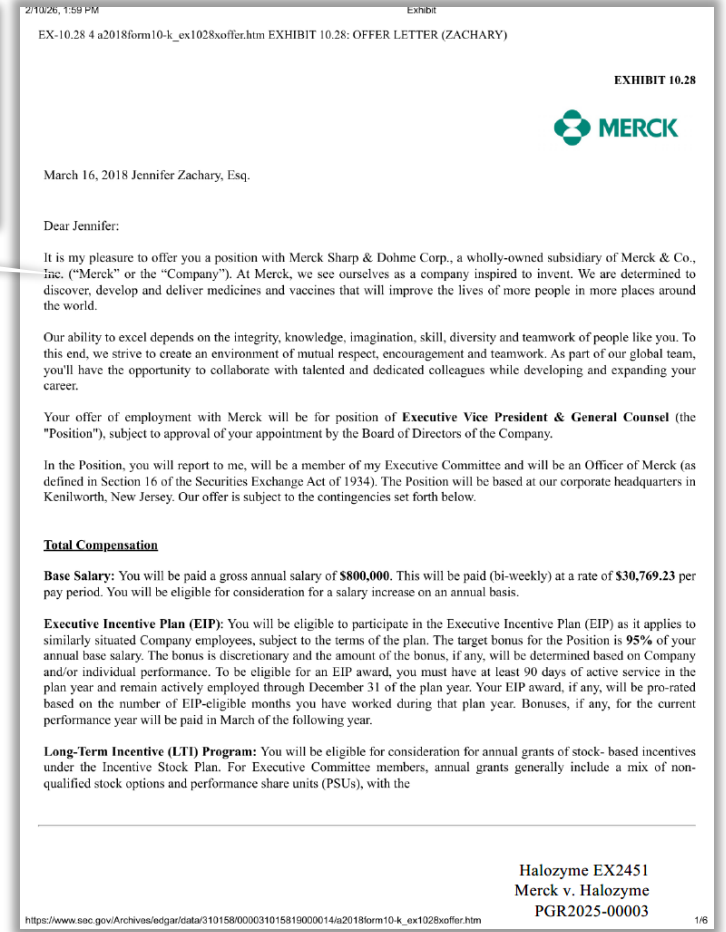


Opp. at 13; EX2401; EX2426-2444

CONFIDENTIAL – PROTECTIVE ORDER MATERIAL

Jennifer Zachery Is Employed and Paid by MSD LLC

It is my pleasure to offer you a position with **Merck Sharp & Dohme Corp.**, a wholly-owned subsidiary of Merck & Co., Inc. ("Merck" or the "Company"). At Merck, we see ourselves as a company inspired to invent. We are determined to discover, develop and deliver medicines and vaccines that will improve the lives of more people in more places around the world.



Opp. at 9-11

CONFIDENTIAL – PROTECTIVE ORDER MATERIAL

PGR2025-00003/4/6/9

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Officers Can Wear Two Hats Without Creating an RPI Issue

- “Directors and officers holding positions with a parent and its *subsidiary can and do ‘change hats’ to represent the two corporations separately*, despite their common ownership.” *Daifuku Co. Ltd. v. Murata Machinery, Ltd.*, IPR2015-01538, Paper 11 at 9-11 (PTAB Jan. 19, 2016) (quotation omitted).
 - “[E]vidence as a whole must establish that the nonparty possessed effective control over a party’s conduct ... as measured from a practical, as opposed to a purely theoretical, standpoint.” *Id.*
 - “[T]he evidence [fails to] show that Par Co. exerts control over this proceeding merely because Par Co. and Petitioner are in a similar business and the same person has roles in both Par Co. and Par Inc.” *Horizon*, IPR2015-01117, Paper 13 at 10.
- There is no basis to conclude that Ms. Zachary has a “fiduciary duty *to control the* [proceedings] on behalf of both entities.” *RODE Microphones, LLC v. Zaxcom, Inc.*, IPR2025-00230, Paper 61 at 13 (PTAB Jan. 21, 2026).

Opp. at 1, 9-10; EX2402; EX2403

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Halozyme’s Motion Relies on Misinterpreting Public Documents

11/13/25, 12:35 PM

nrk-20250930

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

FORM 10-Q

11/13/25, 12:35 PM

nrk-20250930

Part I. Financial Information
Item 1. Financial Statements

MERCK & CO., INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF INCOME
(Unaudited, \$ in millions except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Sales	\$ 17,276	\$ 16,657	\$ 48,611	\$ 48,544
Costs, Expenses and Other				
Cost of sales	3,855	4,080	10,831	11,365
Selling, general and administrative	2,833	2,731	7,835	7,952
Research and development	4,234	5,862	11,903	13,354
Restructuring costs	47	56	676	256
Other (income) expense, net	(238)	(162)	(281)	(151)
	10,531	12,567	30,964	32,778
Income Before Taxes	6,745	4,090	17,647	15,766
Taxes on income	958	929	2,346	2,377
Net income	5,787	3,161	15,301	13,389
Less: Net income attributable to Noncontrolling Interests	2	4	10	4
Net income attributable to Merck & Co., Inc.	\$ 5,785	\$ 3,157	\$ 15,291	\$ 13,385
Basic Earnings per Common Share Attributable to Merck & Co., Inc.	\$ 2.32	\$ 1.25	\$ 6.09	\$ 6.08
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 2.32	\$ 1.24	\$ 6.08	\$ 6.07

MERCK & CO., INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
(Unaudited, \$ in millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net income attributable to Merck & Co., Inc.	\$ 5,785	\$ 3,157	\$ 15,291	\$ 13,385
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized gain (loss) on derivatives, net of reclassifications	170	(296)	(457)	
Benefit plan net gain (loss) and prior service credit (cost), net of amortization	74	(13)	48	
Cumulative translation adjustment	(25)	289	152	
	219	(10)	(257)	
Comprehensive income attributable to Merck & Co., Inc.	\$ 6,004	\$ 3,147	\$ 15,034	\$ 13,385

The accompanying notes are an integral part of these condensed consolidated financial statements.

- 3 -

https://www.sec.gov/Archives/edgar/data/310156/000031015625000093/nrk-20250930.htm

2/13/26, 11:39 AM

(37) Li Su | LinkedIn

Li Su | Patent Counsel at Merck & Co., Inc.

Merck & Co., Inc.

Beijing University

34 connections

Message

Activity

4 following

Li Su commented on a post by Congress: #

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

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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

Reciprocity under 37 CFR § 11.6(c)

No

Showing 1-1 of 1

No. 22-148

IN THE
Supreme Court of the United States

JACK DANIEL'S PROPERTIES, INC.,

Petitioner,

vs.

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

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HALOZYME EX2446
Merck v. Halozyme
PGR2025-00003

Mot. at 1-3, 8-13, 14-15, 17, 18; Reply at 1-4

CONFIDENTIAL – PROTECTIVE ORDER MATERIAL

Halozyme's RPI Argument Is Built on Non-Definitive Sources

- LinkedIn pages (EX2449), speaker listings (EX2448), organizational websites (EX2447), amicus brief (EX2466) and OED listings (EX2416; EX2465) are not dispositive of which party controls the PGRs.
- Evidence such as “a printed page from LinkedIn” purporting to show an in-house attorney was employed by parent, rather than subsidiary did not lead the Board to find parent was an RPI. *Amneal Pharms., LLC v. Jazz Pharms., Inc.*, Case IPR2015-00545, Paper 25 at 10-14 (PTAB July 29, 2015).
 - Prior to November 2009, what is now MSD LLC was Merck & Co., Inc. (“Old Merck”).
 - In 2009, “Schering-Plough was renamed ‘Merck & Co., Inc.’ [‘New Merck’] and Old Merck, renamed **Merck Sharp & Dohme Corp.**, became a wholly-owned subsidiary of New Merck).” EX1235.
 - In 2022, **Merck Sharp & Dohme Corp.**, became **Merck Sharp & Dohme, LLC**. EX1166-1167.
 - “New Merck” (i.e., “MCI”) is [REDACTED] EX2401.

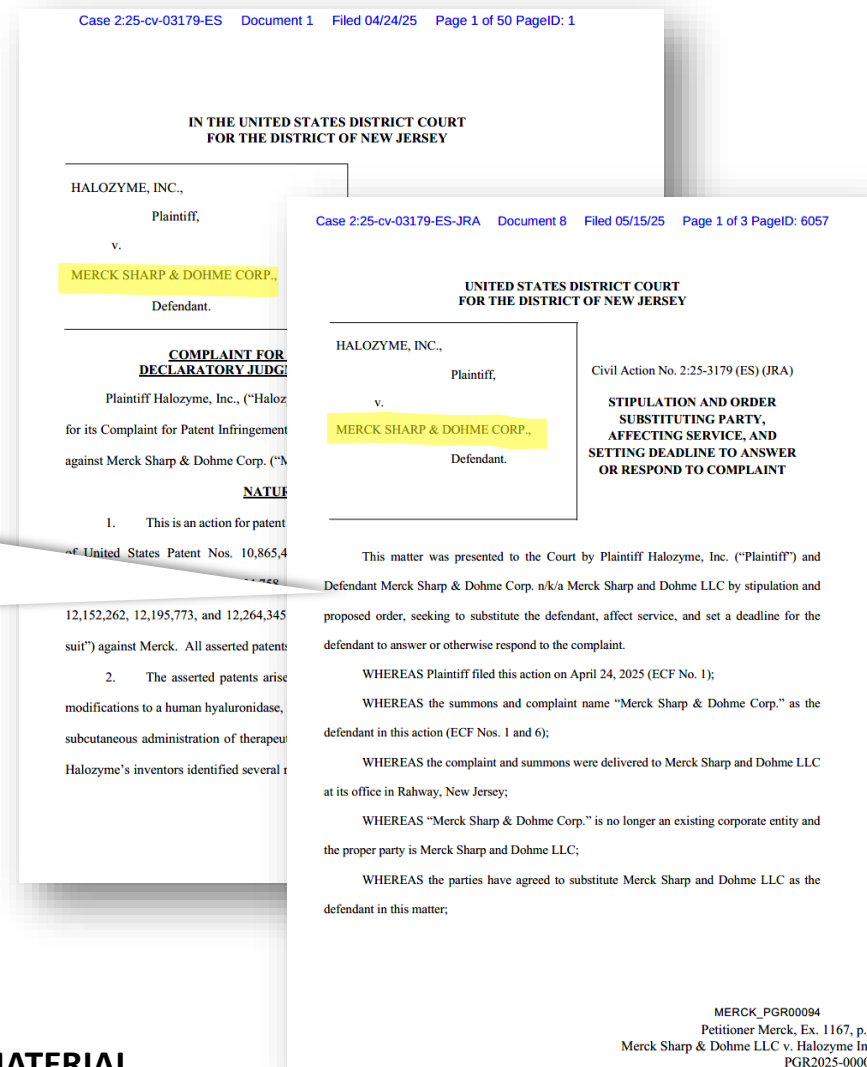
Halozyme's RPI Argument Mischaracterizes SEC Filings

- “Company,” in SEC filings refers to “Merck & Co., Inc. *and its subsidiaries.*” EX2415, 131.
 - “Specifically, the use of the term ‘we’ in an SEC filing, even if used deliberately when referring to what could be the current Petition, does not establish adequately that [parent] has control over this proceeding.” *Par Pharm., Inc. v. Horizon Therapeutics, Inc.*, IPR2015-01117, Paper 13 at 10 (PTAB Nov. 4, 2015)
 - “[S]tatements of [parent corporation] in its Annual Reports about other litigation involving the Petitioner” do not “prove that [parent corporation] is able to control the actions of Petitioner in this proceeding.” *D-Link Sys. Inc. v. Chrimar Sys., Inc.*, IPR2016-01425, Paper 15, at 8 (PTAB Jan. 17, 2017)
- Article III courts have rejected SEC filings as evidence of jurisdiction over corporate parents.
 - *Tahaya Misr Inv., Inc. v. Helwan Cement S.A.E.*, 2016 WL 9024808 (C.D. Cal. May 23, 2016); *Bellomo v. Pa. Life Co.*, 488 F. Supp. 744 (S.D.N.Y. 1980); *Darrick Enters. v. Mitsubishi Motors Corp.*, 2007 WL 6813810, at *6 (D.N.J. Jan. 19, 2007)
- Statements in SEC filings about the “MDASE” dispute do not indicate that MCI took, or could have taken, any action relating to the PGRs. EX2036; EX1166; EX1167.

Halozyme's New Jersey Suit Supports MSD LLC as the Sole RPI

- Halozyme sued only MSD LLC in the MDASE litigation relating to Keytruda® QLEX™, which includes 12 of the PGR-challenged patents.
- Halozyme was aware that MCI is the parent of MSD LLC in that litigation no later than July 2025 when MSD LLC served corporate disclosures.

This matter was presented to the Court by Plaintiff Halozyme, Inc. ("Plaintiff") and Defendant Merck Sharp & Dohme Corp. n/k/a Merck Sharp and Dohme LLC by stipulation and proposed order, seeking to substitute the defendant, affect service, and set a deadline for the defendant to answer or otherwise respond to the complaint.

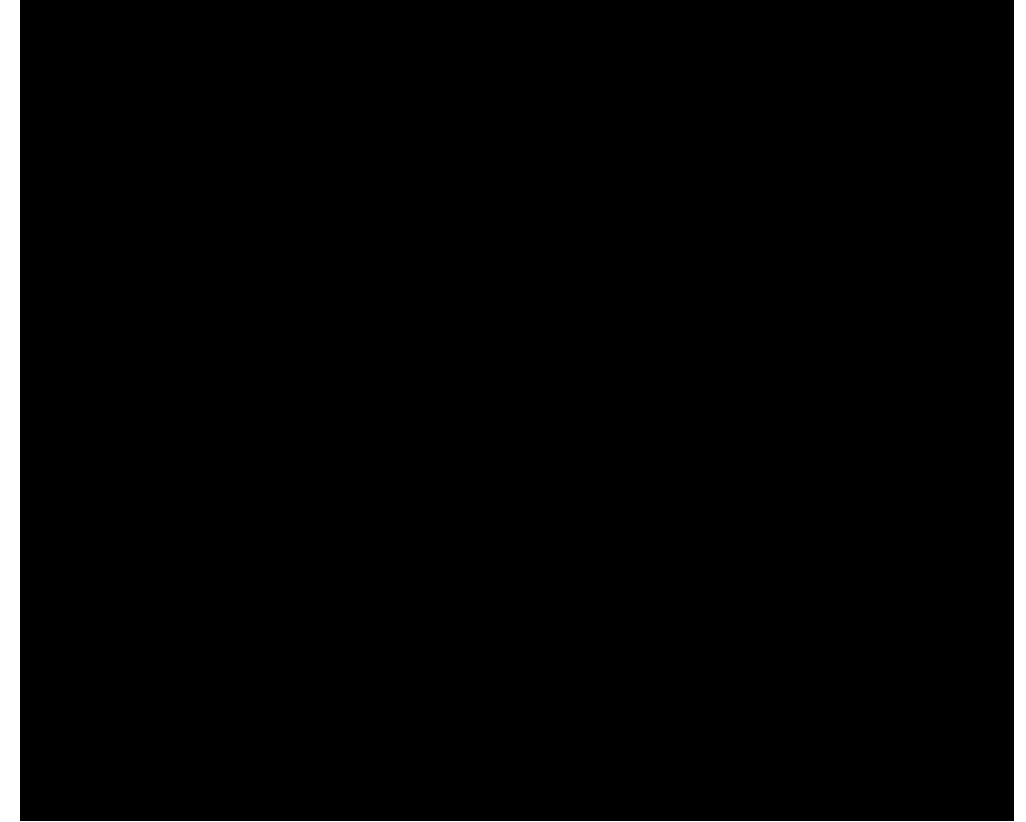


Opp. at 5-7; EX2036; EX1166-1168

CONFIDENTIAL – PROTECTIVE ORDER MATERIAL

MCI Could Not Control the PGRs

- MCI has [REDACTED] EX2401, 15.
- MSD LLC is one of hundreds of subsidiaries worldwide. EX1237.
- “[E]vidence of a common address and telephone number, substantial overlap of officers, and the other evidence on which Patent Owner relies, establishes a relationship between *parties*; it does not establish a relationship between [the parent] and this *proceeding*.” *Daifuku*, IPR2015-01538, Paper 11 at 10-11.



EX1244, 2

Halozyme Misrepresents the MCI and MSD LLC Boards

KENILWORTH, N.J. – Merck (NYSE: MRK), known as MSD outside the United States and Canada, has been operating in the United States under the name Merck for 125 years. To protect our long-established brand rights in the United States, we are filing a lawsuit against Merck KGaA, Darmstadt, Germany, operating as the EMD Group in the United States, regarding their improper use of the name “Merck” in the United States.

EX1241

1/5/26, 2:11 PM

Board of directors - Merck.com



Company > Leadership > Board of directors

Board of directors

Our board of directors brings diverse perspectives, skills and areas of expertise important to fostering the company's business success. The board is dedicated to effective oversight of the business and the key risks facing the company.


Robert M. Davis


Douglas M. Baker, Jr.


Thomas H. Glaser


Surenchid L. Karandhi


Paul B. Rothman, M.D.


Patricia F. Russo


Kathy J. Warden

Dates prior to the merger of Merck & Co., Inc. ("Merck") and Schering-Plough Corporation ("Schering-Plough") on November 3, 2009, reflect membership on the board of Merck (Glaxo) or legacy Schering-Plough (Rust), as the case may be.

Corporate governance documents

[Policies of the board - a statement of Merck's corporate governance principles](#)

[Certificate of incorporation](#)

<https://www.merck.com/company-overview/leadership/board-of-directors/>

1/5/26, 2:11 PM

Board of directors - MSD



Company > Leadership > Board of directors

Board of directors

Our board of directors brings diverse perspectives, skills and areas of expertise important to fostering the company's business success. The board is dedicated to effective oversight of the business and the key risks facing the company.


Robert M. Davis


Douglas M. Baker, Jr.


Mary Ellen Cox


Pamela J. Craig


Thomas H. Glaser


Surenchid L. Karandhi


Rita J. Lantieri-Mourry, M.D.


Stephen L. Mayo, Ph.D.


Paul B. Rothman, M.D.


Patricia F. Russo


Christine E. Seidman, M.D.


Inge G. Thulin


Kathy J. Warden

Dates prior to the merger of Merck & Co., Inc., Rahway, NJ, USA ("MSD") and Schering-Plough Corporation ("Schering-Plough") on November 3, 2009, reflect membership on the board of legacy MSD (Glaxo) or legacy Schering-Plough (Rust), as the case may be.

Related links

<https://www.msd.com/company-overview/leadership/board-of-directors/>

Halozyme EX2409
Merck v. Halozyme
PGR2025-00003

1/2

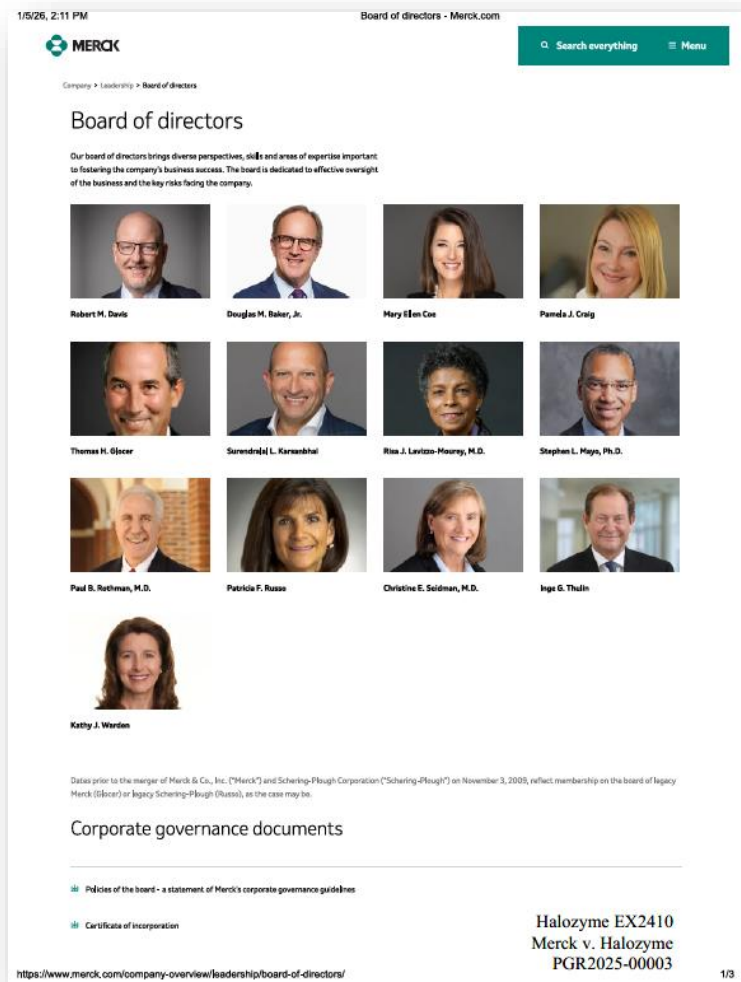
EX2410

EX2409

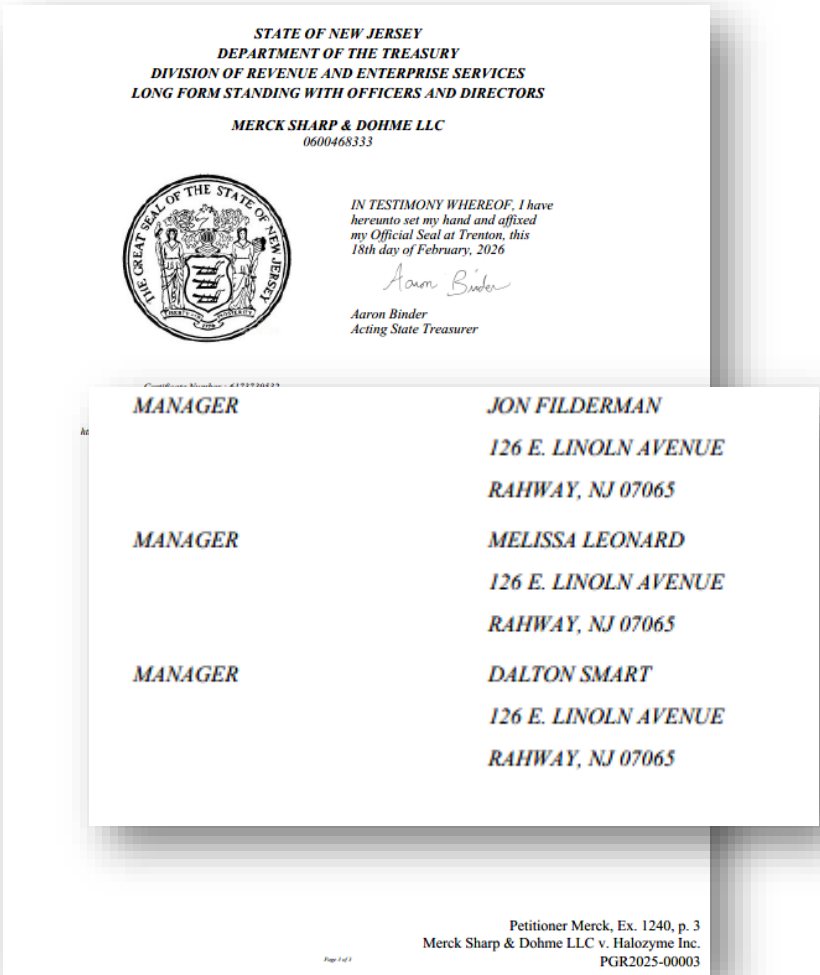
Opp. at 17-18; Mot. at 15

CONFIDENTIAL – PROTECTIVE ORDER MATERIAL

MCI and MSD LLC Have Different Boards



EX2410; EX1243



EX1240; EX1243

Halozyme's Theories Do Not Support MCI as RPI

Gonzalez and applied in *Galderma*. As stated in *Gonzalez*, the evidence as a whole must establish that “the nonparty possessed effective control over a party’s conduct . . . as measured from a practical, as opposed to a purely theoretical, standpoint.” 27 F.3d 759 (emphasis added). Theoretical, hypothetical, or speculative assertions about effective control, unsupported by evidence, are neither probative nor persuasive. Every corporate parent has the theoretical power to control its subsidiaries. See *U.S. v. Bestfoods*, 524 U.S. at 61–62. If theoretical power, whether exercised or not, were the controlling test for determining a real party in interest, the test would be eviscerated of substance.

Trials@uspto.gov
Tel: 571-272-7822

Paper 11
Entered: January 19, 2016

IPR2015-01538
Patent 6,113,341

a common address and telephone number, substantial overlap of officers, and the other evidence on which Patent Owner relies, establishes a relationship between parties; it does not establish a relationship between Daifuku Holdings and this proceeding.

Petitioner relies on *Galderma S.A. v. Allergan Industrie, SAS*, Case IPR2014-01422, (PTAB Mar. 5, 2015) (Paper 14) (quoting *Gonzalez v. Banco Cent. Corp.*, 27 F.3d 751, 759 (1st Cir. 1994)) for the general proposition that “a non-party may be an RPI where it has ‘the power—whether exercised or not—to call the shots.’” Sur-Reply 1. This selective quote, while accurate, does not state the complete legal principle analyzed in *Gonzalez* and applied in *Galderma*. As stated in *Gonzalez*, the evidence as

must establish that “the nonparty possessed effective control over a party’s conduct . . . as measured from a practical, as opposed to a purely theoretical, standpoint.” 27 F.3d 759 (emphasis added). Theoretical, hypothetical, or speculative assertions about effective control, unsupported by evidence, are neither probative nor persuasive. Every corporate parent has the theoretical power to control its subsidiaries. See *U.S. v. Bestfoods*, 524 U.S. at 61–62. If theoretical power, whether exercised or not, were the controlling test for determining a real party in interest, the test would be eviscerated of substance.

In discussing the issue of whether a party is a real party in interest for purposes of an *inter partes* review, the Office Patent Trial Practice Guide cites *Gonzalez*. 77 Fed. Reg. 48,759. As explained in *Gonzalez*, “the concept of substantial control can be illustrated better by examples than by linguistic constructs.” *Gonzalez*, 27 F.3d at 759. For instance, substantial control has been found where a liability insurer assumes the insured’s

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Any Benefit to MCI from the PGRs Is Only from MSD LLC's Success

- “[M]ere benefit is not the standard for determining whether a party is an RPI.” *Bowtech, Inc., v. MCP IP, LLC*, IPR2019-00379, Paper 14 at 23 (P. TAB July 3, 2019)
- A parent of a subsidiary “always ‘has a preexisting, established relationship with the petitioner’ and is likely to benefit when and to the degree that its subsidiary benefits [M]ere establishment of parent-company status is insufficient to render a non-party an RPI.” *Puzhen Life USA, LLC v. ESIP Series 2, LLC*, IPR2017-02197, Paper 24 at 9 (PTAB Feb. 27, 2019).
- MCI has no separate interest from MSD LLC. See *Nuseed Ams. Inc. v. BASF Plant Sci. GMBH*, IPR2017-02176, Paper 16 at 11 (PTAB Apr. 11, 2018).

Halozyme's Inexcusable Delay

1. DUE DATE 1

Patent Owner may file—

a. A response to the petition (37 C.F.R. § 42.120). If Patent Owner elects not to file a response, Patent Owner must arrange a conference call with the parties and the Board. Patent Owner is cautioned that any arguments not raised in the response may be deemed waived.

b. A motion to amend the patent (37 C.F.R. § 42.121).

Trials@uspto.gov
571-272-7822

Paper 26
Date: June 2, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEALS BOARD

MERCK SHARP & DOHME LLC
Petitioner,

v.

HALOZYME, INC.,
Patent Owner.

PGR2025-00003
Patent 11,952,600 B2

Before JEFFREY N. FREDMAN, SUSAN L. ...
CYNTHIA M. HARDMAN, *Administrative Patent Judge*
FREDMAN, *Administrative Patent Judge*.

SCHEDULING ORDER

PGR2025-00003
Patent 11,952,600 B2

specifically identifying the changed due dates, must be promptly filed. The parties may not stipulate an extension of DUE DATES 4, 7, and 8.

In stipulating different times, the parties should consider the effect of the stipulation on times to object to evidence (37 C.F.R. § 42.64(b)(1)), to supplement evidence (§ 42.64(b)(2)), to conduct cross-examination (§ 42.53(d)(2)), and to draft papers depending on the evidence and cross-examination testimony.

1. DUE DATE 1

Patent Owner may file—

a. A response to the petition (37 C.F.R. § 42.120). If Patent Owner elects not to file a response, Patent Owner must arrange a conference call with the parties and the Board. Patent Owner is cautioned that any arguments not raised in the response may be deemed waived.

b. A motion to amend the patent (37 C.F.R. § 42.121).

2. DUE DATE 2

Petitioner may file a reply to the Patent Owner's response.

Petitioner may file an opposition to the motion to amend.

3. DUE DATE 3

Patent Owner may file a sur-reply to Petitioner's reply.

Patent Owner may also file either:

a. a reply to the opposition to the motion to amend and/or preliminary guidance (if provided); or

b. a revised motion to amend.

NOTE: If Patent Owner files neither of the above papers (a reply to the opposition or a revised motion to amend), and the Board has issued preliminary guidance, Petitioner may file a reply to the preliminary

Halozyme Waived the RPI Issue by Failing to Raise It in Any of its PORs

PGR	Patent	POR
PGR2025-00003	11,952,600	9/23/2025
PGR2025-00004	12,018,298	10/7/2025
PGR2025-00006	12,152,262	10/8/2025
PGR2025-00009	12,123,035	10/9/2025
Oct. 28, 2025: Corning designated precedential		
Nov. 12, 2025: Halozyme first raises RPI allegations		
PGR2025-00017	12,110,520	1/6/2026
PGR2025-00033	12,049,652	1/7/2026
PGR2025-00039	12,104,185	1/8/2026
PGR2025-00046	12,091,692	1/9/2026
PGR2025-00030	12,054,758	1/12/2026
PGR2025-00052	12,264,345	1/13/2026
PGR2025-00024	12,060,590	1/14/2026
PGR2025-00042	12,037,618	1/15/2026
PGR2025-00050	12,077,791	1/16/2026
PGR2025-00053	12,195,773	1/20/2026

Halozyme fails to
raise RPI in its later PORs

Opp. at 23-25

CONFIDENTIAL – PROTECTIVE ORDER MATERIAL