

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) PGR2025-00030 (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)

**PATENT OWNER'S REPLY IN SUPPORT OF MOTION TO TERMINATE
PROCEEDINGS FOR FAILURE TO NAME ALL REAL PARTIES-IN-
INTEREST**

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I. MERCK & CO. IS A REAL PARTY-IN-INTEREST

A. Merck & Co. [REDACTED]

MSD asserts that its parent, Merck & Co. (MCI), [REDACTED] [REDACTED]. Opp., 1, 8, 21-22; EX1244, 2; EX2401, 15. But Merck & Co. has Executive officers, including Jennifer Zachery as General Counsel, as well as a Board of Directors. Opp., 17-18; EX1243, 1-2; *see also* PO Motion to Terminate (MTT), 15. [REDACTED] [REDACTED]. MTT, 15; EX2463, 66. MSD does not dispute that Merck & Co. sells KEYTRUDA[®] and KEYTRUDA QLEX[™] and pays licensing fees for rights to patents covering KEYTRUDA QLEX[™]. Opp., 22; MTT, 2, 18-19.

Thus, Merck & Co. is not merely a “holding company”—it is *the* company (with people located at an address and phone number) that one will find doing a public search on the internet about Merck in New Jersey. EX2411; EX2412.

B. Ms. Zachary, General Counsel for both companies, [REDACTED] and the SEC filings discussing them

MSD oddly asserts that “[a]lthough Ms. Zachary also serves as General Counsel to MCI as an officer, she is not an MCI employee.” Opp., 9. MSD admits that in her capacity as Merck & Co.’s General Counsel, Ms. Zachary has “signed multiple SEC filings on behalf of MCI,” i.e., filings that say that Merck & Co. filed these PGRs. Opp., 9; EX2400, 25; EX2454, 22. It is undisputed that [REDACTED] [REDACTED].

Opp., 9-10. She has been acting as General Counsel for both MSD and Merck & Co. at the exact same time. *Id.* And she described her job at *Merck and Co.* as her “principal occupation” in documents filed with the SEC. EX2462 at 6, 12-13. Thus, it cannot be that her direct role in, and Merck & Co.’s ability to control, these PGRs “are pure theory,” as MSD alleges. Opp. 20.

C. The term “the Company” in SEC filings clearly refers to “Merck & Co., Inc.” and not its subsidiaries, such as MSD

When Merck & Co. intended the term “Company” in SEC documents to encompass subsidiaries, it knew how to do so. *See, e.g.*, EX2415, 75; EX1234, 4; EX2415, 104-105 (distinguishing between “the Company” and “its subsidiary Merck Sharp & Dohme LLC. (MSD)”). By stark contrast, the first page of FY 2024 Form 10-K refers to “Merck & Co., Inc. (Merck or the Company),” consistent with definitions in other filings. EX2415, 1; EX2400, 6; EX2454, 6.

MSD refers to page 131 of Merck & Co.’s FY 2024 Form 10-K (EX2415), which is part of an auditor’s report provided by PricewaterhouseCoopers LLP (“PWC”). Opp., 5, 14 (citing EX2415, 131). This audit report is a separate document in its own right. EX2415, 131-132. PWC’s report says PWC audited “Merck & Co., Inc. and its subsidiaries (the “Company”).” *Id.*, 131. But that definition applies to PWC’s report, not the SEC document, which provides its own definition of “Company.” EX2415, 1. Notably, Merck & Co. does not include a similar audit report nor make any such statements in its Nov 2025 filing (EX2400).

D. MSD’s discussion of “Merck” and “MSD” websites and other evidence indicate Ms. Zachary directs and controls subsidiaries

MSD indicates that the www.merck.com and www.msd.com websites identify Merck & Co’s executive team and board members for both “Merck” and “MSD,” i.e., two names for Merck & Co. Opp., 17-18. Ms. Zachary’s bios for “Merck” and “MSD” (EX2458, EX2460) say 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.”

But how can Ms. Zachary set Merck & Co.’s “global legal strategy” if Merck & Co. has no employees? MSD’s assertions and evidence suggest she must do it through employees of subsidiaries and their legal departments. *See* Opp., 11 (“MCI conducts substantially all of its operations through its subsidiaries.”). In other words, Ms. Zachary directs and controls Merck & Co. subsidiaries, such as MSD, and employees of subsidiaries like MSD report to her.

E. SEC filings, Supreme Court *amicus* brief, LinkedIn page, and IPO’s Board of Director membership are not “speculative” or “incorrect”

MSD suggests that much evidence, including SEC filings, provide “speculative (and incorrect) inferences.” Opp., 2. Such evidence (*see, e.g.*, cited in MTT, 2, 14-16) says what it says and is relevant, especially in the aggregate.

F. Facts here differ from those in case law MSD cites

MSD also cites a number of cases that present facts clearly distinguishable from those in these PGRs. For example, many of MSD’s cited cases came out

before *AIT*, 897 F.3d 1336 (Fed. Cir. 2018) and *RPX*, IPR2015-01750, Paper 128 (precedential Dec. 4, 2020), and before the designation of *Corning*, which addresses, e.g., an opportunity to control and blurred corporate lines. *Corning*, 15.

Many facts here distinguish these PGRs from cases MSD cites. Such facts include, e.g., (1) SEC statements stating Merck & Co. (“the Company”) filed these PGRs, EX2400, 25; (2) [REDACTED] [REDACTED]. EX2402, 8; EX2403, 8; and (3) evidence indicating—and MSD does not dispute (*see* Opp., 22)—Merck & Co. has a large interest in, and greatly benefits, from these PGRs. *See* MTT, 18-19. Moreover, MSD’s cited cases relating to corporate “veil piercing” are not relevant to determining RPI. Opp., 16-17; *AIT*, 897 F.3d at 1351 (“Congress intended that the term ‘real party in interest’ have its expansive common-law meaning.”).

G. Activity in other cases cited by MSD is irrelevant to MSD’s burden.

MSD attempts to avoid its burden on RPI by referring to Halozyme actions as a plaintiff in D.N.J. litigation, as if they are relevant to MSD’s obligations here. Opp., 7. Also, Quinn Emanuel attorneys in the prior cases differ from those representing Halozyme, and an ethical wall is in place, i.e., any knowledge of Quinn Emanuel’s MSD team cannot be imputed to the Halozyme team.

H. Funding, blurred corporate lines, and benefit

MSD admits that Merck & Co.’s Legal Defense Reserves “are kept in order

to protect against legal losses to ensure MCI and its subsidiaries are adequately capitalized.” Opp. 14. This is entirely consistent with Merck & Co. funding MSD and losses it might see, e.g., in litigation related to these PGRs.

As discussed previously (MTT, 14-16), evidence relating to [REDACTED]

[REDACTED]—is highly relevant. At minimum, this evidence shows [REDACTED]

[REDACTED]. *See also* Opp., 21. This presents strong evidence of blurred lines.

Merck & Co. has a large interest in, desires, and greatly benefits from these PGRs. *See* MTT, 18-19, discussing, e.g., (1) Merck & Co.’s sales relating to KEYTRUDA[®] and KEYTRUDA QLEX[™], and (2) Merck & Co.’s exclusive license and royalty payments for a key component of KEYTRUDA QLEX[™]. MSD does not dispute these facts. Opp., 22.

II. HALOZYME TIMELY RAISED THE ISSUE OF RPI.

Case law cited by MSD (Opp., 24-25) fails to suggest Halozyme waived the RPI issue (*see* MTT, 5-4, 20). *See Recor Med.*, IPR2022-00431, Paper 53 (denying Director Review without analysis); *RODE*, IPR2025-00230, Paper 61 at 3-4 (agreeing “triggering events did not occur” until *Corning* was designated); *Interactive*, IPR2024-00465, Paper 36 (pre-dating the designation of *Corning*, which itself addresses RPI after a POR was filed, *see Corning*, Papers 24 and 31).

Respectfully submitted,

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CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

I certify that the above-captioned **PATENT OWNER'S REPLY IN SUPPORT OF MOTION TO TERMINATE PROCEEDINGS FOR FAILURE TO NAME ALL REAL PARTIES-IN-INTEREST** was served in its entirety on February 26, 2026, upon the following parties via electronic mail:

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