

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 BRIEF ON TESTIMONY OF MS. KELLY GREZ

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TABLE OF NAMED INDIVIDUALS **(including in portions of transcript cited)**

Kelly Grez, MCI Corporate Secretary / MSD Assistant VP, Legal	passim
Jennifer Zachary, MCI / MSD General Counsel, MCI Executive VP and officer/MSD Executive VP	1, 4, 5
Dalton Smart, MCI Global Controller / MSD President, Manager	2–3
Anthony Wildasin, MCI / MSD Asst. Corporate Secretary	2–3
Melissa Leonard, MCI Treasurer / MSD Senior VP, Treasurer, Manager	2–3
Timothy Dillane, MCI / MSD Assistant Treasurer	2–3
Mark Walker, MCI / MSD Assistant Treasurer	2–3
Robert Smartwood, MCI / MSD Assistant Treasurer	2–3
Robert Davis, MCI Chairman and CEO (and MSD “employee”)	3, 4–5
Kenneth Frazier, (former) MCI Chairman and CEO (and MSD “employee”)	3
Jon Filderman, MSD Vice President, Manager	2–3
Gary A Henningsen, MSD Senior VP, Corporate Tax	2–3
Karen R. Ettelman, MSD Assistant Secretary	2–3
Mark Stewart, MSD Vice President of Global IP Litigation	4, 5
Laura Ginkel, MSD Senior Vice President and Asst. General Counsel	5

Merck & Co., Inc. (“MCI”) is an RPI. Petitioner MSD has the burden to show otherwise, and MSD was authorized to submit a declaration to address holes in the record. But Petitioner’s declaration, by MCI corporate secretary Kelly Grez, merely reiterated Petitioner’s position that [REDACTED]

[REDACTED]¹

Those assertions do not address the relevant questions Petitioner and its witness failed to answer. What is relevant: MCI is not an uninterested, independent parent. Instead, as Ms. Grez confirms, MCI and MSD are a united enterprise, with MCI exercising control over and operating through MSD, through blurred lines of separation. In fact, MCI appoints MSD’s controlling managers, and MSD is run by personnel with dual MCI/MSD roles, [REDACTED]. In fact, MCI’s corporate documents delegate control, including over patent matters, to dual-role personnel. Thus, MCI officer/MSD employee Ms. Zachary can settle these proceedings. MCI is an RPI.

¹ Indeed, Ms. Grez did not discuss in her declaration MSD’s governing LLC agreement [REDACTED]

[REDACTED]. EX1225, 53:3-24. Ms. Grez was evasive or unable to answer when asked questions about that relationship. *Id.*, 105:10-116:7, 60:22-61:12.

I. MCI AND MSD “ARE NOT INDEPENDENT PARTIES” AND OPERATE AS A UNITED ENTERPRISE UNDER MCI’S CONTROL

MCI is a publicly traded “global pharmaceutical company with more than \$200 billion in market cap” that oversees the operations of its subsidiaries. EX1225, 57:16-19, 126:16-20, 129:6-15. MCI “is responsible for the global enterprise ... [and] the business of that enterprise is conducted through subsidiaries,” including MSD. *Id.*, 271:19-272:6, 124:14-130:5, 106:21-107:6, 139:4-22; EX2410. MSD is the “main U.S. operating entity for [MCI’s] human health business,” (*id.*, 58:10-13), and operates on behalf of MCI throughout the globe. Due to this arrangement, as admitted by Ms. Grez, MCI and MSD “[a]re not independent parties.” *Id.*, 85:17-23.

Specifically, MCI and MSD are a united enterprise with MCI controlling MSD and operating through it. MSD’s LLC agreement establishes that MSD is controlled by a board of managers; but as Ms. Grez testified, as the “sole owner of MSD,” MCI is “charged with appointing” those very same managers and can remove them. EX1225, 53:6-17, 55:6-25, 63:17-25, 65:8-67:12. Further underlining MCI’s control, two of the three MSD managers appointed by MCI are, in fact, MCI officers. *Id.*, 347:10-23, 348:18-23. For instance, MSD’s president and manager, Dalton Smart, is MCI’s global controller. *Id.*, 347:10-16.² Similarly, MSD’s “day-to-day

² Further underscoring the blurred lines of corporate separation, MCI’s job postings state that MCI is “also known” as MSD LLC. *Id.*, 334:17-339:16.

operations are managed by [MSD] officers,” but—like the managers—seven of these officers are MCI personnel. *Id.*, 54:10-54:17, 348:3-365:15.

Because there is such extensive overlap, MCI—as the sole owner of MSD—exercises full control over and operates through MSD [REDACTED]. In fact, Ms. Grez performs both her MCI and MSD roles using the same office, desk, computer, email, and phone, without notifying colleagues when she allegedly “switches” roles. EX1225, 87:5-90:13. She has a single performance evaluation for both roles. *Id.*, 77:14-78:6.

While MSD and Ms. Grez emphasize [REDACTED]³ that does not mean MCI lacks control over MSD. Instead, *all* MCI officers are *also* MSD “employees.” EX1225, 94:6-25, 258:18-259:17, 356:9-365:15. MCI officers/MSD employees execute MCI’s board of directors’ “guidance on formulating plans for business and strategies” for the “global enterprise” “as a whole.” *Id.* 126:2-127:9.

II. MCI MANAGES THE GLOBAL ENTERPRISE’S IP PROCEEDINGS, INCLUDING THESE PGRs, THROUGH MSD

MCI’s oversight and responsibilities extend to MSD’s “blockbuster” product KEYTRUDA and KEYTRUDA QLEX, including this litigation. MCI’s “global enterprise” clearly intends to benefit from these PGRs on patents asserted in the

³ Ms. Grez testified that “as companies, you operate through the employees” (EX1225, 105:6-9) but could not define what an “employee” means. *Id.*, 345:15-16.

related QLEX infringement litigation.

KEYTRUDA is MSD and MCI's "best selling product" "by far" (\$30 billion in 2025; EX2036, ¶68). EX1225, 148:9-15, 188:6-8. And MCI's oversight responsibilities extend to the follow-on product KEYTRUDA QLEX, which MCI's officers have told investor analysts will take 30-40% of KEYTRUDA's massive market. EX1225 157:3-18, 165:13-166:4, 175:7-181:15. Indeed, the MCI Board's research committee is responsible for "drug and vaccine discovery, [and] development and licensing efforts" by its subsidiaries. EX1225, 138:19-140:7.

MCI's control extends directly to these PGRs, which relate to QLEX. Specifically, consistent with its hand-in-glove arrangement, Ms. Grez admitted that MCI centrally coordinates its global IP litigation, including international proceedings against Halozyme, through MSD: "IP is primarily run out of Merck Sharp & Dohme LLC" [REDACTED] (EX1225, 192:6-18, 197:4-199:6) that MSD/MCI did not produce. *Id.*, 191:7-192:18, 97:15-98:24, 100:11-101:15, 315:9-316:6. MSD thus "run[s]" MCI's global litigation because MCI delegated the power to do so to MSD via agreement, consistent with MCI's delegation of authority concerning patents generally.

Specifically, as Ms. Grez testified, MCI passed resolutions authorizing dual-role MCI officers/MSD employees—including Mr. Davis and Ms. Zachary (both of whom have dual roles)—to "execute and to revoke" documents related to *any* patent

matters, including with respect to litigation, on behalf of both MCI *and* its affiliates, including MSD. *Id.*, 241:20–246:18, 252:6-257:11, 258:18-259:4.

Ms. Zachary in particular has “responsibility” for litigation, including these PGRs, and authority to settle them. *Id.*, 105:10-105:21, 304:12-305:19, 307:18-308:22. And she is responsible for “advis[ing] the board of directors of Merck & Co., Inc. on the global enterprise impact” “in her capacity as general counsel of Merck & Co., Inc.,” using legal advice from MSD’s attorneys. *Id.*, 235:5-236:5, 99:12-101:15, 237:8-17, 295:3-15. In short—and as must be the case to manage a global enterprise—MCI authorized MSD and Ms. Zachary to run these proceedings.

Ms. Grez points to international proceedings (EX1224, ¶34) to suggest MCI’s subsidiaries operate independently of MCI. But she admits such proceedings are centrally “run” through Mark Stewart, who MCI authorized to act on its behalf. EX1225, 191:7-193:3, 241:20–248:4, 250:22-251:21. In fact, though Mr. Stewart is an MSD employee, his title is “VP of Global IP Litigation” and Ms. Grez admits he “has global responsibilities.” *Id.*, 191:3-192:24. Consistent with MCI’s control of MSD, and inconsistent with the incredible suggestion that MCI would not coordinate its global litigations, Mr. Stewart attended a German proceeding between MCI (not MSD) and Halozyme, on behalf of “Merck,” not MSD. *Id.*, 205:18-210:17. MCI uses MSD’s legal operations to serve its own, aligned, global interests in these PGRs. *Id.*, 315:9-316:6, 84:8-86:17, 97:15-98:24, 99:21-101:15. MCI is an RPI.

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

I certify that the above-captioned **PATENT OWNER'S BRIEF ON TESTIMONY OF MS. KELLY GREZ** was served in its entirety on April 2, 2026, upon the following parties via electronic mail:

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