

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)

**PETITIONER'S SUPPLEMENTAL BRIEF IN OPPOSITION TO PATENT
OWNER'S MOTION TO TERMINATE**

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Amneal Pharms., LLC v. Jazz Pharms., Inc.,
Case IPR2015-00545, Paper 25 (PTAB July 29, 2015)4

Daifuku Co. Ltd. v. Murata Machinery, Ltd.,
IPR2015-01538, Paper 11 (PTAB Jan. 19, 2016)2

Other Authorities

PGR2025-00003, Paper 1143

Across a ten-hour day, with seven hours on the record and 17 new exhibits introduced, Halozyme pressed Kelly Grez, Assistant Vice President, Legal, and Secretary of Petitioner Merck Sharp & Dohme LLC (“MSD LLC”) and Corporate Secretary of Merck & Co., Inc. (“MCI”), to concede that MCI has the authority to terminate and control these PGRs.¹ EX1225, 288:19-293:3; 296:17-297:1, 293:20-295:15, 102:12-105:9, 105:22-116:7, 299:2-24, 300:9-303:4, 304:3-10, 305:4-11. But Ms. Grez consistently testified that was not true—MCI has no practical way or reason to do so. *E.g., Id.*, 98:21-24, 291:24-293:3, 277:8-19, 289:6-18, 115:7-116:7, 106:5-109:8, 110:6-14, 113:14-21. Her testimony unequivocally establishes that MCI cannot control these PGRs. MCI is a [REDACTED] [REDACTED]. EX1224, ¶¶ 7-9, 23; EX1225, 108:24-110:14, 113:14-21, 115:14-116:7, 291:19-293:3, 288:19-289:18, 293:20-294:5. Indeed, Ms. Grez was unaware of the MCI Board ever discussing these PGRs or Halozyme’s dispute with MSD LLC. EX1225, 144:11-146:2.

I. MCI Is Not Involved and Has No Capacity to Be Involved in the PGRs

MCI oversees the global enterprise of its subsidiaries at the *governance* level; it [REDACTED] *Id.*, 108:18-109:8, 289:14-18, 299:21-

¹ Petitioner reserves its right to seek to exclude passages of new exhibits that were simply read into the record. *E.g.*, EX1225, 156:8-162:2; 166:18-167:16.

24. Operations [REDACTED] *Id.*, 105:22-106:20, 136:13-137:4; 114:8-24, 100:24-101:10, 115:7-22, 115:24-116:7. MCI does not [REDACTED]
[REDACTED]
[REDACTED] *Id.*, 103:9-21, 106:21-110:14.
MCI [REDACTED] *Id.*, 98:21-24. Ms. Grez has attended “a portion of all of ... the meetings of the board of directors of Merck & Co., Inc. in the past two years,” and is unaware of MCI’s board [REDACTED]
[REDACTED] *Id.*, 144:11-146:2. She believed it is [REDACTED]
[REDACTED] *Id.*, 145:23-146:2, 146:22-24. [REDACTED]
[REDACTED] *Id.*, 311:5-9.

A. MCI and MSD LLC Are Structured as Separate Companies

MSD LLC has a three-member Board of Managers which manages its day-to-day affairs. EX1224, ¶ 10. MCI could have structured MSD LLC to operate under MCI’s direction, but it did not, which confirms the two entities’ independence. EX1225, 53:6-55:9, 65:5-23. Whether MCI could, from a “purely theoretical, standpoint,” appoint or remove managers in an attempt to influence litigation is not evidence of effective control of these proceedings, and there is no evidence MCI has attempted to exert any influence here (including through MSD LLC’s Board of Managers). *Daifuku Co. Ltd. v. Murata Machinery, Ltd.*, IPR2015-01538, Paper 11 at 9-11 (PTAB Jan. 19, 2016); EX1225, 57:8-58:23, 331:23-332:2.

B. MSD LLC Oversees the PGRs Without MCI’s Involvement

MSD LLC, as the U.S. operating entity for the human health business, is [REDACTED]. EX1224, ¶ 9. MSD LLC’s in-house patent counsel, Mark Stewart, Eric Majchrzak, Laura Ginkel, and Li Su, are the only individuals involved in these PGRs. EX1225, 100:24-101:10; EX1224, ¶ 17; EX2401, 9. Official records confirm each is employed only by MSD LLC. EX1224, ¶ 17; EX2404; EX2430-2435.

Mr. Stewart manages the PGRs. EX1225, 306:4-9. He “does not report to [MCI]”; he reports to [REDACTED]. [REDACTED] *Id.*, 193:12-194:9, 316:7-317:6. MSD LLC is also the only entity that will directly benefit from these PGRs. MSD LLC is the holder of the BLA for KEYTRUDA QLEX™ in the United States, the product against which Halozyme has asserted twelve PGR-challenged patents. EX1224, ¶¶ 26-27; EX2036, ¶ 3. KEYTRUDA QLEX™, sold by MSD LLC in the U.S., accounts for only \$40 million (1.3%) of a combined \$31.7 billion in revenue for KEYTRUDA products. EX1225, 185:7-186:7; EX2467, 1. Contrary to Halozyme’s allegations, MCI is not [REDACTED]. [REDACTED] [REDACTED] (EX1224, ¶ 28). PGR2025-00003, Paper 114 at 12:23-13:4; EX1225, 322:25-323:3, 326:22-327:14.

None of the documents Halozyme cites refutes any of the above facts. MTT

Reply, 5. The use of “Merck” and “Merck and Co.,” by MSD LLC employees may, in part, be explained by the fact that what is now MSD LLC was once called “Merck & Co., Inc.” EX1224, ¶¶ 11-14. This is a potential reason for occasional misuse of the “Merck” brand name in the U.S. *Id.*, ¶¶ 15-16. It is not evidence of blurred lines, much less with respect to these proceedings. Official employment records and Ms. Grez’s testimony make clear that the attorneys responsible for these PGRs are not MCI employees, and are not acting on MCI’s behalf. *Amneal Pharms., LLC v. Jazz Pharms., Inc.*, Case IPR2015-00545, Paper 25 at 10-14 (PTAB July 29, 2015) (rejecting RPI argument that relied on LinkedIn and website evidence).

C. Ms. Zachary Only Directs Legal Operations as GC of MSD LLC

Ms. Zachary is an employee of MSD LLC as General Counsel. EX1224, ¶¶ 18-19; EX1225, 91:19-21, 92:11-94:25. Her [REDACTED] I. EX1224, ¶ 18. She is also an officer, but not an employee, of MCI. *Id.*, ¶¶ 18, 20; EX1225, 92:5-10. As Ms. Grez (who also holds two roles) explained, these roles are separate and distinct. EX1224, ¶¶ 21-23; EX1225, 80:9-83:15, 84:8-85:5, 92:5-10, 97:8-98:24. [REDACTED]
[REDACTED]
[REDACTED] EX1224, ¶¶ 22, 24-25; EX1225, 294:21-295:7, 295:16-21, 98:5-24, 100:6-14. [REDACTED]
[REDACTED] EX1224, ¶ 23; EX1225, 97:13-19.

Because MCI [REDACTED], Ms. Zachary does not control these PGRs on MCI's behalf. EX1225, 314:8-315:8, 346:18-347:5, 100:6-14, 98:5-24. [REDACTED]

[REDACTED] *Id.*, 307:18-308:22, 105:10-21, 294:24-295:21, 311:23-312:16, 313:13-20, 330:18-331:22. [REDACTED]

[REDACTED] EX2401, 9; EX1225, 316:7-19, 319:1-320:5, 321:19-322:6.

II. SEC Filings Do Not Show MCI's Involvement in these PGRs

Halozyme ignores that the word "Company" in MCI's SEC filings refers to the consolidated enterprise of MCI *and* its subsidiaries. EX1224, ¶¶ 29-36; EX1225, 129:23-130:5, 187:4-11, 287:2-22, 329:18-330:3, 176:24-177:13, 195:14-23. MCI shareholders invest in that *consolidated* enterprise, and MCI's SEC filings endeavor to present information "in a way that is clear and accessible to investors," which does not require correlating actions with subsidiaries in all cases. EX1225, 49:11-19, 121:10-19; EX1224, ¶¶ 31-32. Although SEC filings state "the Company began filing" these PGRs and the "Company" was sued by Halozyme, MSD LLC is the only entity in those proceedings. EX1166-1167; EX1224, ¶¶ 34-36. MSD LLC also [REDACTED]. EX1224, ¶¶ 8, 37.

III. Conclusion

Ms. Grez's testimony confirms that Halozyme's motion should be denied.

Dated: April 2, 2026

Respectfully Submitted,
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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 2nd day of April 2026, I caused to be served a true and correct copy of the foregoing and any accompanying exhibits by email on the following counsel:

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