**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyme Inc.,
Patent Owner.

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| 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) |

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**DECLARATION OF KELLY GREZ**

I, Kelly Grez, declare as follows:

1. I make this declaration on behalf of Petitioner Merck Sharp & Dohme LLC in support of its Opposition to Patent Owner's Motion to Terminate in the above-captioned proceedings.

2. I hold the positions of Assistant Vice President, Legal, and Secretary at Merck Sharp & Dohme LLC and Corporate Secretary at Merck & Co., Inc.

3. In my role as Assistant Vice President, Legal, at Merck Sharp & Dohme LLC, I am familiar with its legal department, personnel, business, and the manner in which its legal matters, including these Post-Grant Review ("PGR") proceedings before the Patent Trial and Appeal Board, are directed and managed.

4. Through my role as Corporate Secretary of Merck & Co., Inc., I am familiar with Merck & Co., Inc.'s governance documents, its Board of Directors, the general responsibilities of its officers, and its corporate structure.

5. By virtue of holding concurrent roles at both companies, I am personally familiar with the responsibilities and functions of officers who serve in capacities at both companies. I am acquainted with how those roles and responsibilities differ between Merck & Co., Inc. and Merck Sharp & Dohme LLC. I make this declaration on the basis of my personal knowledge and practical familiarity with the business of Merck & Co., Inc. and its subsidiary Merck Sharp & Dohme LLC, as well as my review of the corporate records, governance

documents, and other materials referenced herein that I have familiarized myself with in order to provide this declaration.

### A. Corporate Structure of Merck & Co., Inc. and Merck Sharp & Dohme LLC

6. Merck & Co., Inc. and Merck Sharp & Dohme LLC are separate and distinct legal entities. Although Merck & Co., Inc. is the sole owner of Merck Sharp & Dohme LLC, the two companies have separate governance structures, and their own sets of officers and directors.

7. Merck & Co., Inc., formerly known as Schering-Plough Corporation, is a corporation organized and existing under the laws of New Jersey with its principal place of business in New Jersey. *See* EX1244; EX1238. Merck & Co., Inc. is a publicly traded company that functions [redacted] and is the parent to hundreds of subsidiaries throughout the world. *See* EX1237.

8. Merck & Co., Inc. is a [redacted] *See* EX1244 at 2 ([redacted]). Merck & Co., Inc. has [redacted].

9. Consistent with its [redacted] structure, Merck & Co., Inc.'s subsidiaries [redacted] Merck Sharp & Dohme LLC is an operating subsidiary of Merck & Co., Inc., organized under the

laws of New Jersey with its principal place of business in New Jersey. *See* EX1237 at 13; EX1240. Merck Sharp & Dohme LLC is the main operating entity in the United States for the human health business.

10. Merck Sharp & Dohme LLC's governing board is separate from Merck & Co., Inc.'s governing board. Merck Sharp & Dohme LLC has a three-member Board of Managers. EX1240 at 2. Merck & Co., Inc. has a thirteen-member Board of Directors. *See* EX2410. There is no overlap in personnel between Merck Sharp & Dohme LLC's Board of Managers and Merck & Co. Inc.'s Board of Directors. *See* EX1243; EX1240 at 2.

### B. Merck Entity Name Changes Over Time And In Different Countries

11. The names of Merck entities have changed over time. On November 3, 2009, the company then known as "Merck & Co., Inc." completed a merger with a subsidiary of Schering-Plough Corporation (the "Schering-Plough merger"). Prior to the Schering-Plough merger, Merck & Co., Inc. was an operating entity.

12. Following the Schering-Plough merger, the entity that was formerly known as "Merck & Co., Inc." ("Old Merck") was renamed Merck Sharp & Dohme Corp. *See* EX1235 at 2. Thus, references to "Merck & Co., Inc." prior to November 2009 refer to "Old Merck," which became Merck Sharp & Dohme Corp., not the current Merck & Co., Inc.

13. In May 2022, Merck Sharp & Dohme Corp. changed its corporate form from a corporation to a limited liability company and became Merck Sharp & Dohme LLC. *See* EX1166; EX1167. References to "Merck Sharp & Dohme Corp." after the Schering-Plough merger was completed but prior to May 2022 refer to the entity that is now Merck Sharp & Dohme LLC. *See* EX1166; EX1167.

14. As part of the Schering-Plough merger, Schering-Plough Corporation was renamed Merck & Co., Inc. and became the publicly traded parent holding company that is now Merck & Co., Inc. *See* EX1235 at 2.

15. Due to a dispute over use of the name "Merck" with an unrelated German company "Merck KGaA," Merck & Co., Inc. and its subsidiaries do not use the name "Merck" in countries outside of the United States and Canada. *See* EX1241. As such, Merck & Co., Inc. and its subsidiaries are branded as "MSD" outside of the United States and Canada. The website for Merck & Co., Inc. and its subsidiaries in the United States is "merck.com." "Msd.com" is their global website.

16. Both the "merck.com" and "msd.com" websites have "Leadership" pages which identify the officers and Board of Directors of Merck & Co., Inc. EX2407; EX2408; EX2409; EX2410. Neither website identifies the officers or the Board of Managers of Merck Sharp & Dohme LLC.

### C. Merck Sharp & Dohme LLC Employees

17. I am generally familiar with the members of Merck Sharp & Dohme LLC's legal department. I understand that the individuals identified below have been identified as involved in and/or overseeing the current PGR proceedings. *See* EX2401 at 9. As is confirmed [redacted], all of these individuals are employed exclusively by Merck Sharp & Dohme LLC, and none is an employee of Merck & Co., Inc.:

- Mark Stewart, Vice President, Global Intellectual Property Litigation. *See* EX2404 at 1; EX2430; EX2434.
- [redacted]

### D. Jennifer Zachary

18. Jennifer Zachary is an employee of Merck Sharp & Dohme LLC. EX1236; EX1242. [redacted] *See* EX1242. Ms. Zachary is not an employee of Merck & Co., Inc.

19. Ms. Zachary holds two distinct roles, which she exercises in separate capacities. First, she serves as Executive Vice President and General Counsel of

Merck Sharp & Dohme LLC. *See* EX2451 at 1; EX1236; EX1242; EX2402 at MERCK_PGR000013.

20. Second, she serves in an officer role as Executive Vice President and General Counsel to Merck & Co., Inc. *See* EX2458; EX2451 at 1-2; EX2462 at 13.

21. Ms. Zachary's two roles are separate and distinct. When Ms. Zachary acts on behalf of Merck Sharp & Dohme LLC, she does so pursuant to her employment as Executive Vice President and General Counsel of Merck Sharp & Dohme LLC, not as an officer of Merck & Co., Inc. When Ms. Zachary acts on behalf of Merck & Co., Inc., she does so pursuant to her authority as an officer of Merck & Co., Inc. and not as an employee of Merck Sharp & Dohme LLC.

22. Ms. Zachary directs the legal operations of Merck Sharp & Dohme LLC in her capacity as an employee and General Counsel of Merck Sharp & Dohme LLC. *See* EX2402 at MERCK_PGR000013; EX2403 at MERCK_PGR00063. When Ms. Zachary works with Merck Sharp & Dohme LLC's legal department, including its in-house litigation and intellectual property counsel (such as the individuals identified in paragraph 17 above), she does so exclusively in her capacity as an employee of Merck Sharp & Dohme LLC. This includes any decisions she makes or advice she gives, as the case may be, regarding whether to initiate, pursue, continue or terminate patent litigation or patent proceedings.

23. The Merck & Co., Inc. [redacted] Further, in her role at Merck & Co., Inc., Ms. Zachary's responsibilities are to serve the Merck & Co., Inc. entity and its Board, not to direct and oversee Merck Sharp & Dohme LLC's legal operations, including its in-house counsel.

24. Ms. Zachary's interactions with the Merck Sharp & Dohme LLC employees who have overseen these PGR proceedings—namely, [redacted] Mr. Stewart, [redacted]—have occurred exclusively in Ms. Zachary's capacity as General Counsel of Merck Sharp & Dohme LLC. *See* EX2401 at 9.

25. In her capacity as General Counsel of Merck Sharp & Dohme LLC, Ms. Zachary [redacted] EX2402 at MERCK_PGR000013; EX2403 at MERCK_PGR00063. [redacted] EX2426; EX2427; EX2428.

### E. KEYTRUDA QLEX™ (pembrolizumab + berahyaluronidase alfa-pmph)

26. Merck Sharp & Dohme LLC is the only entity that [redacted] It is also the only entity that [redacted]

27. [redacted]. This includes:

- **Regulatory submissions**: Holder of the Biologics License Application ("BLA") No. 761467 for KEYTRUDA QLEX™;
- [redacted]

28. Merck & Co., Inc. is [redacted] Nor does Merck & Co., Inc. have [redacted] Such obligations rest with Merck & Co., Inc.'s subsidiaries. Merck Sharp & Dohme LLC is the [redacted]

**F. Merck & Co., Inc.'s SEC Disclosures**

29. As a publicly traded company, Merck & Co., Inc. must file reports with the Securities and Exchange Commission ("SEC") regarding its and its

subsidiaries' financial condition, performance, and other reportable events. *See* EX2400; EX2415; EX2454; EX2466.

30. Officers of Merck & Co., Inc. such as Ms. Zachary and myself sign SEC filings on behalf of Merck & Co., Inc., and we act as officers of Merck & Co., Inc. when performing that task. *See* EX2454 at 47; EX2415 at 142; EX2466 at 4; EX2467; EX2468.

31. Merck & Co., Inc. is the publicly traded parent company, and it provides consolidated reports on behalf of itself and all its subsidiaries. When Merck & Co., Inc.'s SEC filings use the terms "the Company" or "Merck," those references describe the consolidated enterprise of Merck & Co., Inc. and all of its subsidiaries. Statements made about "the Company" in these filings are not intended to be attributed specifically or exclusively to Merck & Co., Inc. itself. EX2415 at 131. This is standard practice in Merck & Co., Inc.'s consolidated SEC filings, which explain that they are consolidated reports that gather and report information from Merck & Co., Inc. and its subsidiaries taken together. EX2400 at 3, 6; EX2415 at 75.

32. Merck & Co., Inc. has an obligation to present its disclosures in a way that is clear and accessible to investors and the investing public. The consolidated presentation of legal proceedings implicating Merck & Co., Inc.'s subsidiaries under the umbrella of "the Company" or "Merck" serves that investor-focused

purpose of identifying material litigations in an accessible way. It is not intended as an indication to the investing public that Merck & Co., Inc. is itself involved in those legal proceedings.

33. For example, the disclosure of the matters involving Halozyme Inc., including the PGR proceedings, relates only to Merck Sharp & Dohme LLC. *See* EX2454 at 22. As is apparent on the face of the referenced legal documents, Merck Sharp & Dohme LLC, not Merck & Co., Inc., is the only defendant in the district court litigation filed by Halozyme, Inc. in the United States District Court for the District of New Jersey. *See Halozyme, Inc. v. Merck Sharp & Dohme LLC*, No. 25-cv-03179 (D.N.J). Although Merck & Co., Inc.'s SEC filings describe "the Company" in relation to this litigation, the disclosure is specific to Merck Sharp & Dohme LLC's role as a defendant. This is standard practice for a public company, for the reasons I explained above in paragraphs 31 and 32.

34. As another example, Merck & Co., Inc.'s 10-Q filing with the SEC for the Quarter ended September 30, 2025 states the "Company filed revocation actions against EP Patent No. 2 797 622 (the '622 patent) owned by Halozyme, Inc. in the UK, France, Germany and The Netherlands." EX2400 at 25. These revocation actions were brought by subsidiaries of Merck & Co., Inc. In the UK, the revocation action was brought by Merck Sharp & Dohme (UK) Limited. *See Merck Sharp & Dohme (UK) Ltd. v. Halozyme Inc.*, HP-2025-000041 (in the High

Court of Justice, Business and Property Courts of England and Wales, Intellectual Property List, Patents Court). In France, the revocation action was brought by MSD France. *MSD France v. Halozyme Inc.*, Docket No. 25/09063 (Paris Judicial Court). In Germany, the revocation action was brought by MSD Sharp & Dohme GmbH. *MSD Sharp & Dohme GmbH v. Halozyme Inc.*, Docket No. 3 Ni 13/25 (EP) (German Federal Patent Court). In the Netherlands, the revocation action was brought by Merck Sharp & Dohme B.V. *Merck Sharp & Dohme B.V. v. Halozyme Inc.*, No. C/09/695432 (Dist. Ct. Hague).

35. As a further example, Merck & Co., Inc.'s 10-Q filing with the SEC for the Quarter ended June 30, 2025 discusses patent infringement litigation filed by the "Company" in the District of New Jersey and the Northern District of West Virginia relating to BRIDION®. EX2454 at 21. The BRIDION® lawsuits were brought by subsidiaries of Merck & Co., Inc. and Merck & Co., Inc. was not a party to the litigation. *See Merck Sharp & Dohme B.V., Organon USA Inc. v. Aurobindo Pharma USA, Inc. et al.*, 20-cv-02576 (D.N.J.); *see also Merck Sharp & Dohme B.V., Organon USA Inc. v. Mylan Pharms. Inc. et al.*, No. 20-cv-00061 (N.D.W. Va.); *Merck Sharp & Dohme B.V., Merck Sharp & Dohme, LLC v. Aurobindo Pharma USA, Inc. et al.*, Case No. 23-2254 (Fed. Cir.).

36. As a matter of practicality and internal processes, when preparing SEC disclosures about material legal proceedings, including patent litigation and

PGR proceedings (such as those involving Halozyme), employees of the relevant operating subsidiary are contacted for information and updates on such legal proceedings. More specifically, in the context of the Halozyme litigation and these PGR proceedings, I understand that Merck Sharp & Dohme LLC employees, including Mark Stewart, provide the information that is included in Merck & Co., Inc.'s SEC disclosures.

37. Finally, the "Legal Defense Reserves" identified in Merck & Co., Inc.'s consolidated SEC disclosures are likewise reported on a consolidated basis. EX2400 at 26; EX2454 at 23. For example, the $220 million in legal defense reserves identified in Merck & Co., Inc.'s 10-Q, *see* EX2400 at 26, represents reserves [redacted] EX2415; EX2454. Merck & Co., Inc. [redacted]

38. I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge, information, and belief.

Dated: March 12, 2026

Kelly Grez