UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS GENE THERAPIES, INC. & NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner

v.

GENZYME CORPORATION,
Patent Owner.

Case: IPR2023-00608
Patent No. 9,051,542

PATENT OWNER GENZYME CORPORATION'S UNOPPOSED MOTION FOR *PRO HAC VICE* ADMISSION OF KATHERINE A. HELM, J.D., PH.D.

Pursuant to 37 C.F.R. § 42.10(c), the Board's Notice of Filing Date Accorded (authorizing this motion), and the representative order Novartis Gene Therapies, Inc and Novartis Pharmaceuticals Corporation v. Genzyme Corporation, IPR2023-00608, Paper 5 (PTAB March 15, 2023) (concerning the content of a motion for pro hac vice admission), Patent Owner respectfully requests that the Board recognize Katherine A. Helm as counsel *pro hac vice* in this proceeding. Petitioner has indicated it will not oppose this motion.

Statement of Facts

1. Counsel, Katherine A. Helm, is counsel to Patent Owner Genzyme Corporation ("Patent Owner"), as set forth in Patent Owner's Exhibit 2001. Dr. Helm has been providing Patent Owner with privileged legal advice in connection with U.S. Patent No. 9,051,542 ("the '542 patent") and related patents, including in conjunction with *Novartis Gene Therapies, Inc. & Novartis Pharmaceuticals Corporation v. Genzyme Corporation*, IPR2023-00608 and IPR2023-00609, and in connection with co-pending district court litigation between the parties to this proceeding in *Genzyme Corporation and Aventis Inc. v. Novartis Gene Therapies, Inc., et al,* In the United States District Court for the District of Delaware, C.A. No. 18-cv-823-VAC-CJB. I either have appeared or intend to appear *pro hac vice* before the Office in the aforementioned related IPR proceeding identified in Patent Owner's Mandatory

Notices in this case. *Id. at* ¶2.

2. Dr. Helm is partner in the law firm of Dechert LLP and a member of the Litigation Department and the Intellectual Property Group in the New York Office. *Id.* at ¶3. She is and experienced patent litigator and has litigated numerous cases over the past nearly two decades, appearing and acting as counsel and lead counsel in litigation matters before various U.S. District Courts and U.S. Courts of Appeals, including arguing appeals as lead counsel before the U.S. Courts of Appeals for the Federal Circuit, the Fourth Circuit and the Ninth Circuit. *Id.* The majority of these cases have been related to intellectual property disputes and, particularly, patent litigation, in the pharmaceutical and biologics industries. *Id.*

3. Dr. Helm holds a doctorate in a biological science (neuroscience) and spent five years prior to and during law school working as a technical advisor in the Intellectual Property Group of a large New York law firm, where she focused on pharmaceutical and biotechnology patent prosecution, patent litigation and patent counseling. *Id.* at ¶4. She has also worked on a variety of contested proceedings before various patent offices, including interferences before the United States Patent and Trademark Office ("USPTO") Board of Appeals and Interferences, *inter partes* reviews ("IPRs"), post grant reviews ("PGRs") and covered business method patent reviews ("CBMs") before the USPTO's Patent Trial and Appeal Board

("PTAB"), as well as oppositions before the Opposition Division of the European Patent Office ("EPO"), and opposition appeals before the EPO Technical Boards of Appeal. *Id. at*¶4; *see also id.* at ¶6 (prior PTAB proceedings in which Dr. Helm has been admitted *pro hac vice*). The vast majority of these contested proceedings involved patents relating to products in the pharmaceutical or biotechnology industry. *Id.*at ¶4.

4. Given Dr. Helm's current role as counsel for Patent Owner in various patent matters, Dr. Helm has carefully reviewed, developed an extensive familiarity with, and acquired a substantial understanding of the '542 patent and prosecution history, the legal subject matter, the factual and technical subject matter including pharmaceutical formulations, and the prior art and expert testimony presented in Petitioner's request for *inter partes* review of the '542 patent, which forms the basis of this proceeding. *Id.* at ¶ 5.

5. Dr. Helm has been admitted *pro hac vice* before the PTAB seven (7) times, each of which has involved patents in the pharmaceutical industry, in *Eli Lilly & Co. v. Genentech, Inc.*, PGR2019-00043, *BicycleRD Limited v. Pepscan Systems B.V.*, IPR2020-01569, *BicycleRD Limited v. Pepscan Systems B.V.*, IPR2020-01626; and *Kymera Therapeutics, Inc. v. Dana-Farber Cancer Institute, Inc.*, PGR2021-00115; *Dana-Farber Cancer Institute, Inc. v. Bristol-Myers Squibb Company*, IPR2023-00249; and *Dana-Farber Cancer Institute, Inc. v. Bristol-Myers Squibb Company*, IPR2023-00252; and *Dana-Farber*

6. Dr. Helm is a member in good standing in all jurisdictions and courts where she has been admitted to practice. *Id.* at ¶7. This includes the bars in the State of New York, the Commonwealth of Massachusetts, and the District of Columbia, as well as the following courts: the Supreme Court of the United States, the United States Court of Appeals for the Federal Circuit, the United States Courts of Appeals for the Second Circuit, the Third Circuit, the Fourth Circuit, and the Ninth Circuit, as well as United States Court of Appeals for Veterans Claims, the United States District Courts for the Southern and Eastern Districts of New York, and the United States District Court for the District of Massachusetts. *Id.*

7. Finally, Dr. Helm has attested to the remaining elements of paragraph 2(b) of the Representative Order. *Id*. at ¶¶ 8-10. Dr. Helm has never been suspended, disbarred or sanctioned by a court or administrative body. *Id.* at ¶9-10. She has never had a court or administrative body deny her application for admission to practice. *Id.* at ¶8. She has never been sanctioned or cited for contempt by any court or administrative body. *Id.* at ¶10.

8. Dr. Helm has read and will comply with the Office Patent Trial Practice Guide and the Board's Rules of Practice for Trials set forth in Part 42 of 37 C.F.R. *Id*. at ¶¶ 11. Dr. Helm also agrees to be subject to the USPTO Code of

Professional Responsibility set forth in 37 C.F.R. §§ 11.101 *et seq.* and disciplinary jurisdiction under 37 C.F.R. § 11.19(a). *Id*. at ¶12.

9. Patent Owner's lead counsel, Amanda K. Antons, is registered to practice before the United States Patent and Trademark Office ("USPTO") and holds Registration No. 65,236.

Accordingly, good cause exists for the granting of this motion, and Patent Owner respectfully requests that Katherine A. Helm be admitted *pro hac vice*.

Dated: May 26, 2023

Respectfully submitted,

By: */Amanda K. Antons/*

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CERTIFICATE OF SERVICE

I certify that today in:

Novartis Gene Therapies, Inc. & Novartis Pharmaceuticals Corporation v. Genzyme Corporation, IPR2023-00608 (U.S. Patent 9,051,542)

I caused to be served a copy of:

Patent Owner Genzyme Corporation's Unopposed Motion for *Pro Hac Vice* Admission of Katherine A. Helm, J.D., Ph.D.
Exhibit 2001
Certificate of Service

upon:

Novartis Gene Therapies, Inc. & Novartis Pharmaceuticals Corporation, c/o
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via:

electronic service to the email addresses above.

Dated: May 26, 2023

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