

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

**DECLARATION OF KATHERINE A. HELM J.D., PH.D.
IN SUPPORT OF
MOTION FOR ADMISSION *PRO HAC VICE***

I, Katherine A. Helm, declare as follows:

1. I am of age and make this declaration upon my personal knowledge.

2. I am counsel to Patent Owner (“Patent Owner”) Genzyme Corporation. I have 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.

3. I am a 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. I am an experienced patent litigator and have 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 on appeal before the U.S. Courts of Appeals for the Federal Circuit, the Fourth Circuit and the Ninth Circuit. The majority of these cases have been related to intellectual property disputes and, in particular, patent litigation, in the pharmaceutical and biologics industries.

4. I hold a doctorate in a biological science (neuroscience) and I 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 I focused on pharmaceutical and biotechnology patent litigation, prosecution and counseling. My experience includes working on a variety of contested proceedings before various patent offices around the world, 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. The vast majority of these contested proceedings involved patents relating to products in the pharmaceutical industry.

5. I have carefully reviewed, developed an extensive familiarity with, and acquired a substantial understanding of the ’542 patent and its file

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.

6. In the last three (3) years, I have 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 Cancer Institute, Inc. v. E.R. Squibb & Sons, LLC & Ono Pharmaceuticals Co., Ltd.*, IPR2023-0501.

7. I am a member in good standing in all jurisdictions and courts where I have been admitted to practice. 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 Courts of Appeals for the Federal Circuit, the Second Circuit, the Third Circuit, the Fourth Circuit, and the Ninth Circuit, as well as the 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.

8. I have never had any application for admission to practice before the PTAB or any other court or administrative body denied.

9. I have never been suspended or disbarred from practice before the PTAB or any other court or administrative body.

10. I have never had any sanctions or contempt citations imposed on me by the PTAB or any other court or administrative body.

11. I have 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.

12. I agree to be subject to the USPTO Rules of Professional Conduct set forth in 37 C.F.R. §§ 11.101 *et seq.* and disciplinary jurisdiction under 37 C.F.R. § 11.19(a).

13. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: May 26, 2023

Respectfully submitted,

By: /s/Katherine A. Helm
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