

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALVOTECH USA INC. and ALVOTECH HF,
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case: PGR2025-00085
U.S. Patent No. 12,168,036

DECLARATION OF KATHRYN S. KAYALI IN SUPPORT OF
MOTION FOR *PRO HAC VICE* ADMISSION PURSUANT TO 37
C.F.R. § 42.10(c)

1. I, Kathryn S. Kayali, am more than twenty-one years of age, am competent to present this declaration, and have personal knowledge of the facts set forth herein.

2. This declaration is given in support of Patent Owner Regeneron Pharmaceuticals, Inc.'s motion for *Pro Hac Vice* Admission of Kathryn S. Kayali.

3. I am a member in good standing of the bars of Massachusetts and the District of Columbia. My bar membership number for the District of Columbia is 1033382. My bar membership number for the Commonwealth of Massachusetts is 691566. I am also admitted to practice before the United States Court of Appeals for the Federal Circuit. I have been practicing law for more than ten years in the field of patent litigation at the law firm of Williams & Connolly LLP, first as an associate and now as a partner.

4. I have never been suspended or disbarred from practice before any court or administrative body.

5. No court or administrative body has ever denied my application for admission to practice before it.

6. No court or administrative body has ever imposed sanctions or contempt citations on me.

7. 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.

8. I understand and agree that I will be subject to the USPTO Code of Professional Responsibility set forth in 37 C.F.R. §§ 11.101 *et seq.* and will be subject to disciplinary jurisdiction under 37 C.F.R. §§ 11.19(a).

9. In the last three years, I applied to appear *pro hac vice* in the following matters, and in each case my application was granted on the date indicated:

- *Biontech SE & Pfizer Inc. v. Modernatx, Inc.*, IPR2023-01358
(regarding U.S. Patent No. 10,702,600) (application granted
May 7, 2024)
- *Biontech SE & Pfizer Inc. v. Modernatx, Inc.*, IPR2023-01359
(regarding U.S. Patent No. 10,933,127) (application granted
May 7, 2024)

10. I have gained experience with Patent Office rules, regulations, and procedures by participating in the above-listed *inter partes* review proceedings and by litigating cases involving issues of claim construction, allegations of inequitable conduct, and other issues for which review of a patent's prosecution history is essential.

11. I am familiar with the subject matter at issue in the present proceeding. I received a Bachelor's Degree from Yale in Molecular, Cellular, and Developmental Biology and a Master's Degree from the University of Texas at Dallas in Molecular and Cell Biology. These degrees are related to the subject matter

of the challenged patent, and I have established familiarity with the issues in this case by virtue of having:

(i) Reviewed in detail the Patent Owner Preliminary Response, exhibits, and papers filed by Patent Owner in this proceeding;

(ii) Reviewed in detail the challenged patent, U.S. Patent No. 12,168,036;

(iii) Reviewed in detail all pleadings and exhibits filed by Petitioner in this proceeding;

(iv) Reviewed in detail all notices issued by the Board in this proceeding;

(v) Engaged in extensive strategic and substantive discussions regarding this proceeding with Patent Owner's lead and backup counsel;

12. I have reviewed in detail relevant case law and other legal authority related to the allegations made in the Petition.

* * *

I hereby declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and may jeopardize the validity of any application or any patent issuing thereon.

Executed on: May 22, 2026

By: /Kathryn S. Kayali /
Kathryn S. Kayali