

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

PATENT OWNER'S MOTION TO SEAL AND
FOR ENTRY OF DEFAULT PROTECTIVE ORDER

Pursuant to 37 C.F.R. § 42.54 and the Board’s Scheduling Order (Paper 14), Patent Owner Regeneron Pharmaceuticals, Inc. (“Regeneron”) submits this Motion to Seal and for entry of the Default Protective Order (“Motion”) concurrent with the filing of its Patent Owner’s Response (“POR”).

As described in further detail below, the sole exhibit and related citations in an expert declaration and the POR Regeneron moves to seal include information that a third-party service has designated confidential and requested that Regeneron move to seal.

Regeneron conferred with Petitioners Alvotech USA Inc. and Alvotech HF (“Petitioners”), and confirmed that Petitioners do not oppose this Motion.

I. REQUEST TO SEAL CONFIDENTIAL INFORMATION

In a post-grant review, the party moving to seal information must demonstrate “good cause.” 37 C.F.R. § 42.54. The Board has explained that “a movant to seal must demonstrate adequately that (1) the information sought to be sealed is truly confidential, (2) a concrete harm would result upon public disclosure, (3) there exists a genuine need to rely in the trial on the specific information sought to be sealed, and (4), on balance, an interest in maintaining confidentiality outweighs the strong public interest in having an open record.” *Argentum Pharmaceuticals LLC v. Alcon Research, Ltd.*, IPR2017-01053, Paper 27 at 4 (PTAB Jan. 19, 2018) (informative).

A. Documents Requested to be Sealed

Regeneron respectfully moves to seal the following documents:

- **Exhibit 2125:** Exhibit 2125 is a third-party confidential transcript. The transcript (as well as the call itself) is not public and only available to the third-party service's clients. That third-party service has requested that the transcript and its confidential information remain sealed to the public.
- **Exhibit 2051:** The expert declaration of Dr. Bernhardt Trout contains opinions that refer to the confidential information in Exhibit 2125.
- **Patent Owner's Response:** Regeneron's POR contains arguments that refer to the confidential information contained in Exhibit 2125.

Regeneron is prepared to file public versions of Exhibit 2051 and its POR within five business days of the filing of this Motion, or earlier if the Board so requests. Substantially all of Exhibit 2125 is directed to confidential information. Regeneron therefore respectfully requests that Exhibit 2125 remain sealed in its entirety.

B. Good Cause Exists for Sealing Confidential Information

Each of the *Argentum* factors support Regeneron's Motion and a finding of "good cause" here. As noted above, Exhibit 2125 contains confidential information that a third-party service distributes to limited clients. Exhibit 2125 was made available to Regeneron only upon request and has not been made public. Public

disclosure of Exhibit 2125 would risk harm to the third-party service's business. Regeneron has a genuine need to rely on the information sought to be sealed. The information is highly relevant to contesting the obviousness grounds advanced in Alvotech's petition and provides objective indicia of non-obviousness. The information Regeneron moves to seal is narrow, and the public's interest in maintaining a complete and understandable record is fairly balanced by the forthcoming submission of Exhibit 2051 and Regeneron's POR with limited redactions.

For each of these reasons, there is good cause to grant this Motion and seal the above-identified documents.

II. CONCLUSION

Regeneron respectfully requests that the Board seal Exhibit 2125, and confidential versions of Exhibit 2051 and the POR. Regeneron also respectfully requests entry of the Default Protective Order attached as Appendix A.

Date: June 19, 2026

Respectfully submitted,

/David I. Berl/

David I. Berl

Reg. No. 72,751

Williams & Connolly LLP

680 Maine Avenue SW

Washington, D.C. 20024

Lead Counsel for Patent Owner

CERTIFICATE OF SERVICE
(37 C.F.R. § 42.6(e))

The undersigned hereby certifies that on June 19, 2026, I caused a true and correct copy of Patent Owner's Motion to Seal and for Entry of Default Protective Order to be served via e-mail on the following:

Name	E-Mail Address
Martina Hufnal	PGR46514-0017PS1@fr.com
Michael Kane	PGR46514-0017PS1@fr.com
Kristi L. R. Sawert	PGR46514-0017PS1@fr.com
Nitika Fiorella	PGR46514-0017PS1@fr.com
Megan A. Chacon	PGR46514-0017PS1@fr.com
Deanna Reichel	PGR46514-0017PS1@fr.com
Phillip Chen	PGR46514-0017PS1@fr.com

Date: June 19, 2026

/David I. Berl/
David I. Berl
Reg. No. 72,751
Lead Counsel for Patent Owner

APPENDIX A

Default Protective Order

This protective order governs the treatment and filing of confidential information, including documents and testimony.

1. Confidential information shall be clearly marked “PROTECTIVE ORDER MATERIAL.”

2. Access to confidential information is limited to the following individuals who have executed the acknowledgment appended to this order:

(A) Parties. Persons who are owners of a patent involved in the proceeding and other persons who are named parties to the proceeding.

(B) Party Representatives. Representatives of record for a party in the proceeding.

(C) Experts. Retained experts of a party in the proceeding who further certify in the Acknowledgement that they are not a competitor to any party, or a consultant for, or employed by, such a competitor with respect to the subject matter of the proceeding.

(D) In-house counsel. In-house counsel of a party.

(E) Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and

requirements of the Protective Order by the person they are supporting who receives confidential information.

(F) The Office. Employees and representatives of the United States Patent and Trademark Office who have a need for access to the confidential information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

3. Employees (e.g., corporate officers), consultants, or other persons performing work for a party, other than those persons identified above in (2)(A)–(E), shall be extended access to confidential information only upon agreement of the parties or by order of the Board upon a motion brought by the party seeking to disclose confidential information to that person and after signing the Acknowledgment. The party opposing disclosure to that person shall have the burden of proving that such person should be restricted from access to confidential information.

4. Persons receiving confidential information shall use reasonable efforts to maintain the confidentiality of the information, including:

(A) Maintaining such information in a secure location to which persons not authorized to receive the information shall not have access;

(B) Otherwise using reasonable efforts to maintain the confidentiality of the information, which efforts shall be no less rigorous than those the recipient uses to maintain the confidentiality of information not received from the disclosing party;

(C) Ensuring that support personnel of the recipient who have access to the confidential information understand and abide by the obligation to maintain the confidentiality of information received that is designated as confidential; and

(D) Limiting the copying of confidential information to a reasonable number of copies needed for conduct of the proceeding and maintaining a record of the locations of such copies.

5. Persons receiving confidential information shall use the following procedures to maintain the confidentiality of the information:

(A) Documents and Information Filed With the Board.

(i) A party may file documents or information with the Board along with a Motion to Seal. The Motion to Seal should provide a non-confidential description of the nature of the confidential information that is under seal, and set forth the reasons why the information is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The documents or information

shall remain under seal unless the Board determines that some or all of it does not qualify for confidential treatment.

(ii) Where confidentiality is alleged as to some but not all of the information submitted to the Board, the submitting party shall file confidential and non-confidential versions of its submission, together with a Motion to Seal the confidential version setting forth the reasons why the information redacted from the non-confidential version is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The non-confidential version of the submission shall clearly indicate the locations of information that has been redacted. The confidential version of the submission shall be filed under seal. The redacted information shall remain under seal unless the Board determines that some or all of the redacted information does not qualify for confidential treatment.

(B) Documents and Information Exchanged Among the Parties. Documents (including deposition transcripts) and other information designated as confidential that are disclosed to another party during discovery or other proceedings before the Board shall be clearly marked as “PROTECTIVE ORDER MATERIAL” and shall be produced in a manner that maintains its confidentiality.

6. Within 60 days after the final disposition of this action, including the exhaustion of all appeals and motions, each party receiving confidential information must return, or certify the destruction of, all copies of the confidential information to the producing party.

7. Standard Acknowledgement of Protective Order. The following form may be used to acknowledge a protective order and gain access to information covered by the protective order:

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**

Standard Acknowledgment for Access to Protective Order Material

I _____, affirm that I have read the Protective Order; that I will abide by its terms; that I will use the confidential information only in connection with this proceeding and for no other purpose; that I will only allow access to support staff who are reasonably necessary to assist me in this proceeding; that prior to any disclosure to such support staff I informed or will inform them of the requirements of the Protective Order; that I am personally responsible for the requirements of the terms of the Protective Order and I agree to submit to the jurisdiction of the Office and the United States District Court for the Eastern District of Virginia for purposes of enforcing the terms of the Protective Order and providing remedies for its breach.

[Signature]