UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALVOTECH USA INC. and ALVOTECH HF,
Petitioner,

v.

REGENERON PHARMACEUTICALS, INC.,
Patent Owner.

Case PGR2025-00085
U.S. Patent 12,168,036

PETITIONER'S OBJECTIONS TO EVIDENCE

Pursuant to 37 C.F.R. §42.64(b)(1), Petitioner submits the following objections to Patent Owner's Exhibits 2006, 2009, 2019, 2020, 2028, 2029, 2033, 2034, 2040-2043, 2051, 2052, 2125, and 2126 and any reference to or reliance on the foregoing. As required by 37 C.F.R. §42.62, Petitioner's objections below apply the Federal Rules of Evidence (FRE). These objections are being filed within 5 business days of service of the evidence to which the objections are directed. In addition to the objections set forth below, Petitioner maintains all objections to the deposition testimony of Dr. Robert J. Falconer (Ex. 2046) and Dr. Donald J. D'Amico that were preserved by Petitioner during those depositions. Petitioner also reserves the right to move to exclude any objected to exhibits as inadmissible.

I. EXHIBITS 2006, 2009, 2019, 2020, 2028, 2029, 2033, 2034, and 2040-2043

Evidence objected to: Exhibits 2006, 2009, 2019, 2020, 2028, 2029, 2033, 2034, and 2040-2043

Grounds for objection: Exhibits 2006, 2009, 2019, 2020, 2028, 2029, 2033, 2034, and 2040-2043 are not cited in the Patent Owner Response. Nor are these exhibits cited in the Declaration of Dr. Trout (EX2051) or the Declaration of Dr. Bressler (EX2052). Thus, these exhibits lack proper foundation. Petitioner also objects to these exhibits under Fed. R. Evid. 401–403 as irrelevant. Any probative value of these exhibits is substantially outweighed by the danger of unfair prejudice, confusion, and waste of time. Petitioner also objects to these exhibits to the extent

Patent Owner attempts to rely on them through improper incorporation by reference. *See* 37 C.F.R. §42.6(a)(3).

II. EXHIBITS 2125 and 2126

Evidence objected to: Exhibits 2125 and 2126

Grounds for objection: Petitioner objects to Exhibits 2125 and 2126 as being irrelevant under Fed. R. Evid. 401. Petitioner also objects to these exhibits as constituting impermissible hearsay to which no exception applies to the extent that Patent Owner relies on statements in this reference to prove the truth of those statements. *See* Fed. R. Evid. 801–802. Exhibits 2125 and 2126 also have not been authenticated and are not self-authenticating. *See* Fed. R. Evid. 901–903. Nor has testimony been provided showing that these exhibits constitute material that an expert may rely upon and that may be published to a factfinder under Fed. R. Evid. 703. Petitioner objects to these exhibits for lack of foundation and for Patent Owner's failure to authenticate the documents, especially as being publicly available before the critical date, and for Patent Owner's failure to provide a sponsoring witness. *See* Fed. R. Evid. 703, 901.

III. EXHIBITS 2051 and 2052

Evidence objected to: Exhibits 2051 and 2052

Grounds for objection: Petitioner objects to Exhibits 2051 and 2052 to the extent that these exhibits rely on Exhibits 2125 and 2126 to present these hearsay

documents for the truth of any matters set forth in the documents. As set forth above with respect to Exhibits 2125 and 2126, Petitioner objects to each of these exhibits as constituting impermissible hearsay to which no exception applies to the extent that Patent Owner relies on statements in those references to prove the truth of those statements. *See* Fed. R. Evid. 703, 801–802. Moreover, these documents are unauthenticated, and no showing has been made that experts in this field typically rely on such unauthenticated hearsay evidence to render their opinions. *See* Fed. R. Evid. 703, 901–903.

Respectfully submitted,

Dated: 6/26/26

/Kristi L. R. Sawert/

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(Control No. PGR2025-00085)

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §42.6(e), the undersigned certifies that on June 26, 2026, a complete and entire copy of this Petitioner's Objections to Evidence was provided via email to Patent Owner by serving the correspondence email address of record as follows:

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