

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ALVOTECH USA INC. and ALVOTECH HF,  
Petitioners,

v.

REGENERON PHARMACEUTICALS, INC.,  
Patent Owner.

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

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**PATENT OWNER'S OBJECTIONS TO EVIDENCE**

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner Regeneron Pharmaceuticals, Inc. (“Patent Owner”) objects to Petitioner’s Exhibits 1077, 1078, 1079, 1082, 1083, 1084, and 1085, and to any reference to or reliance on those exhibits, served with Petitioner’s Reply to Patent Owner’s Response (Paper 39) (the “Reply”). As required by 37 C.F.R. § 42.62(a), the objections below apply the Federal Rules of Evidence. Petitioner served Paper 39 and Exhibits 1077–1085 (the “reply evidence”) on September 25, 2026. These objections are filed on October 2, 2026, within five business days of that service. Patent Owner maintains all objections to the deposition testimony of Dr. Neil M. Bressler (EX1080) and Dr. Bernhardt L. Trout (EX1081) that were preserved by Patent Owner during those depositions. Patent Owner reserves all rights under 37 C.F.R. § 42.64(c), including the right to move to exclude any objected-to evidence as inadmissible.

**I. EXHIBIT 1077 (Reply Declaration of Dr. D’Amico)**

**Evidence objected to:** Exhibit 1077, Reply Declaration of Donald Joseph D’Amico, M.D., dated September 22, 2026.

**Grounds for objection:**

**Improper Reply Evidence (37 C.F.R. § 42.23(b)).** Patent Owner objects to EX1077 to the extent it presents new testimony about the timing or circumstances of Dr. D’Amico’s work (see EX1077 ¶ 2) that was not provided in his initial declaration (EX1003). This testimony could have been submitted in the Petition or

with EX1003, or after Dr. D’Amico’s deposition and before the filing of Patent Owner’s Response, including in response to Patent Owner’s June 8, 2026 request to Petitioner for routine and/or additional discovery.

**Relevance and Prejudice (Fed. R. Evid. 401–403).** EX1077 is an authentication declaration for the redacted invoice (EX1078). Because every task description in EX1078 is withheld, EX1077’s testimony about the nature and timing of Dr. D’Amico’s work has no independent factual basis; the exhibit does not make the timing or substance of his work more or less probable. Any minimal probative value is substantially outweighed by the risk of misleading the Board into drawing conclusions about work that cannot be evaluated from the redacted invoice.

**Completeness (Fed. R. Evid. 106); Insufficient Basis (Fed. R. Evid. 702–703).** EX1077 relies on EX1078 (the redacted invoice) to support its statements about the timing and nature of Dr. D’Amico’s work. The task descriptions in EX1078 are withheld, yet those descriptions are the portions necessary to evaluate EX1077’s characterization of the work performed. Patent Owner objects under Fed. R. Evid. 106 to the extent Petitioner relies on EX1077’s testimony about the invoice without producing the task descriptions needed to place that testimony in context, and under Fed. R. Evid. 702–703 because the withheld descriptions are the facts and data on which that testimony depends.

## **II. EXHIBIT 1078 (Redacted D’Amico Invoice)**

**Evidence objected to:** Exhibit 1078, redacted invoice of Donald J. D’Amico, M.D., dated September 17, 2025.

### **Grounds for objection:**

**Improper Reply Evidence (37 C.F.R. § 42.23(b)).** Patent Owner objects to EX1078, first submitted with the Reply. The invoice is offered to establish the timing of Dr. D’Amico’s work in response to Patent Owner’s arguments, but the invoice predates Patent Owner’s Response and could have been submitted with the Petition, or at a minimum, shortly after Dr. D’Amico’s deposition or in response to Patent Owner’s June 8, 2026 request to Petitioner for routine and/or additional discovery.

**Relevance and Prejudice (Fed. R. Evid. 401–403).** EX1078 displays dates, hours, rate, and total, but every activity description is redacted. Without those descriptions, the invoice does not establish what work was performed or whether the billed work corresponds to the testimony offered in EX1003 or EX1077. Any minimal probative value is substantially outweighed by the risk of misleading the Board into accepting conclusions about work that cannot be verified from the document.

**Completeness (Fed. R. Evid. 106).** To the extent Petitioner offers EX1078 to show the nature or timing of Dr. D’Amico’s work, Patent Owner objects under

Fed. R. Evid. 106 because the withheld task descriptions are the portions needed to evaluate that use of the invoice. Permitting reliance on a partially redacted invoice risks misleading the Board absent the context those descriptions would provide.

### **III. EXHIBIT 1079 (Reply Declaration of Dr. Falconer)**

**Evidence objected to:** Exhibit 1079, Reply Declaration of Robert John Falconer, Ph.D.

**Grounds for objection:**

**Improper Reply Evidence (37 C.F.R. § 42.23(b)); Improper Incorporation by Reference (37 C.F.R. § 42.6(a)(3)); Relevance and Prejudice (Fed. R. Evid. 401–403); Expert Reliability (Fed. R. Evid. 702–703).** Patent Owner objects to EX1079 to the extent it presents new evidence or opinions beyond responding to Patent Owner’s Response and could have been presented in the Petition or EX1004, Dr. Falconer’s initial declaration, including but not limited to the following:

1. *Preparation testimony (EX1079 § III).* EX1079 states that Dr. Falconer began work in July 2025 and spent more than 30 hours preparing EX1004. Dr. Falconer’s deposition testimony, EX2046, 22:4–24:14, did not provide that timing or work-history detail. Patent Owner objects under 37 C.F.R. § 42.23(b) and Fed. R. Evid. 403 to the extent this new testimony is offered to

rehabilitate Dr. Falconer's preparation history rather than to respond to specific arguments in Patent Owner's Response.

2. *Improper Incorporation by Reference (EX1079 § I).* EX1079 states that Dr. Falconer incorporates his complete EX1004 opinions and references unaddressed opinions of Dr. Trout. Patent Owner objects under 37 C.F.R. § 42.6(a)(3) to these incorporation-by-reference statements to the extent they require the Board to search EX1004 or Dr. Trout's declaration for the substance of the relied-upon opinions without stating and explaining them in EX1079 or Paper 39.

3. *Reliance on Examples 3 and 5 and Figures 3C and 5 of the '036 Patent (EX1079 § IV.C, ¶¶ 23–24; Paper 39 at 23–25).* EX1079 relies on Examples 3 and 5 and Figures 3C and 5 of the '036 patent. This reliance is new to the Reply and was not presented in EX1004. Patent Owner objects under 37 C.F.R. § 42.23(b) because the argument could have been made in the Petition, and under Fed. R. Evid. 401–403 and 702–703 because the opinions relying on this evidence are offered without disclosed testing or validation.

4. *Citation of new references (EX1079 § IV.C, ¶ 25; EX1083).* EX1079 cites Shire (EX1083) for the first time on reply. EX1083 was not cited in the Petition or EX1004. Patent Owner objects under 37 C.F.R. § 42.23(b) to this new reference and under Fed. R. Evid. 401–403 and 702–703 to the extent Dr.

Falconer relies on it substantively without explaining its fit to the high-concentration aflibercept formulations at issue.

5. *Statements outside formulation expertise (EX1079 § IV.A, ¶¶ 9–12).*

Dr. Falconer is presented as an expert in protein formulation, not a clinician. See EX2046, 27:24–28:9 (Dr. Falconer: “[W]ell, I’m definitely not a medical doctor in ophthalmology . . . .”). Patent Owner objects under Fed. R. Evid. 702 to any opinions in EX1079 on clinical or regulatory matters to the extent they are offered without disclosed qualifications, methodology, or factual basis supporting Dr. Falconer’s competence in those areas.

**IV. EXHIBIT 1082 (Vitti Prosecution History, U.S. Patent Publication No. 2016/0144025 A1)**

**Evidence objected to:** Exhibit 1082, prosecution history for U.S. Patent Publication No. 2016/0144025 A1 (Vitti).

**Grounds for objection:**

**Improper Reply Evidence (37 C.F.R. § 42.23(b)).** Patent Owner objects to EX1082, first submitted with the Reply. Paper 39 at 14–15 cites pages 14–15 and 442 of the Vitti prosecution history to support a new argument presented in the Reply. The Petition did not rely on this prosecution history. Because the prosecution history was publicly available at the time of the Petition, submission on reply constitutes improper gap-filling.

**Relevance and Prejudice (Fed. R. Evid. 401–403).** Patent Owner objects to the citation of pages 14–15 and 442 of EX1082. Examiner or applicant statements made in a separate prosecution are offered to characterize Vitti’s disclosure without surrounding context from that proceeding. Any limited probative value is substantially outweighed by the risk of misleading the Board by presenting statements out of context.

**Hearsay (Fed. R. Evid. 801–802).** To the extent Petitioner offers examiner or applicant statements in EX1082 for the truth of the matters asserted, Patent Owner objects under Fed. R. Evid. 801–802. No hearsay exception has been identified.

**V. EXHIBIT 1083 (Shire, Formulation and Manufacturability of Biologics (2009))**

**Evidence objected to:** Exhibit 1083, Steven J. Shire, *Formulation and Manufacturability of Biologics*, 20 Current Opinion in Biotechnology 708 (2009).

**Grounds for objection:**

**Improper Reply Evidence (37 C.F.R. § 42.23(b)).** Patent Owner objects to EX1083, a journal article first submitted with the Reply. Paper 39 at 22 and EX1079 at ¶ 25 cite Shire. This reference was not cited in the Petition or EX1004 and is offered to support a new argument first raised in the Reply.

**Relevance and Prejudice (Fed. R. Evid. 401–403).** EX1083 is a 2009 general-interest review article. Any limited probative value is substantially

outweighed by the risk of misleading the Board into treating a general article as directly relevant to the '036 patent's specific formulation parameters.

**Hearsay (Fed. R. Evid. 801–802).** To the extent Petitioner offers statements in EX1083 for the truth of the matters asserted, Patent Owner objects under Fed. R. Evid. 801–802. No hearsay exception has been identified.

**Expert Reliability (Fed. R. Evid. 702–703).** To the extent Dr. Falconer relies on EX1083 in EX1079 at ¶ 25, Patent Owner objects under Fed. R. Evid. 702–703. The record does not disclose a reliable fit between the general principles in a 2009 review article and the subject matter of the '036 patent.

#### **VI. EXHIBIT 1084 (Australian TGA Approved Form for Product Information)**

**Evidence objected to:** Exhibit 1084, TGA Approved Form for Product Information in Relation to Medicine Under Subsection 7D(1) of the Therapeutic Goods Act 1989, effective March 9, 2018.

#### **Grounds for objection:**

**Improper Reply Evidence (37 C.F.R. § 42.23(b)).** Patent Owner objects to EX1084, first submitted with the Reply. Paper 39 at 15–16 relies on the TGA form as it relates to certain language in the Australian Eylea label (EX1009). This argument is new to the Reply and could have been raised in the Petition.

**Relevance and Prejudice (Fed. R. Evid. 401–403).** EX1084 is a TGA form effective March 9, 2018. The record does not connect this form to the version of the

Australian Eylea label relied upon by Petitioner (EX1009). Without that connection, any limited probative value is substantially outweighed by the risk of misleading the Board into treating requirements from one version as applicable to another.

**Hearsay (Fed. R. Evid. 801–802).** To the extent Petitioner offers the content of EX1084 for the truth of the matters asserted, Patent Owner objects under Fed. R. Evid. 801–802. No hearsay exception has been identified.

**Authentication (Fed. R. Evid. 901–902).** Patent Owner objects to EX1084 under Fed. R. Evid. 901–902 to the extent Petitioner has not authenticated the document as the TGA form it claims to be. EX1084 is a foreign public document unaccompanied by the certification required by Fed. R. Evid. 902(3), and no certified copy or custodial certification under Fed. R. Evid. 902(4) has been provided.

**Lack of Foundation (Fed. R. Evid. 104(b), 703, 901).** Even if authentic, EX1084 is not connected on this record to the specific Australian Eylea label version (EX1009) relied upon by Petitioner. There is no showing that the TGA form effective March 9, 2018, governed the label at the time EX1009 was issued. Patent Owner objects under Fed. R. Evid. 104(b), 703, and 901 because Petitioner has not introduced evidence sufficient to support that connecting fact, and no sponsoring witness has supplied a basis for treating the form as relevant to EX1009.

**VII. EXHIBIT 1085 ('552 Patent Prosecution History, U.S. Patent No. 11,103,552)**

**Evidence objected to:** Exhibit 1085, prosecution history for U.S. Patent No. 11,103,552 (Graham et al.) (the “’552 patent”).

**Grounds for objection:**

**Improper Reply Evidence (37 C.F.R. § 42.23(b)).** Patent Owner objects to EX1085, first submitted with the Reply. Paper 39 at 30 cites pages 499–511 of the ’552 patent prosecution history in support of new arguments raised in the Reply. The Petition did not cite this prosecution history. The prosecution history was publicly available and could have been submitted with the Petition.

**Relevance and Prejudice (Fed. R. Evid. 401–403).** EX1085 is the prosecution history of U.S. Patent No. 11,103,552, a related but distinct patent in the same family as the ’036 patent. Petitioner cites pages 499–511 without explaining how the original claims from that prosecution bear on the issues presented here. Any limited probative value is substantially outweighed by the risk of misleading the Board by presenting statements from a different prosecution without that context.

**Hearsay (Fed. R. Evid. 801–802).** To the extent Petitioner offers statements in EX1085 for the truth of the matters asserted, Patent Owner objects under Fed. R. Evid. 801–802. No hearsay exception has been identified.

**Improper Incorporation by Reference (37 C.F.R. § 42.6(a)(3)).** Patent Owner objects under 37 C.F.R. § 42.6(a)(3) to the extent Paper 39 at 30 cites EX1085

without explaining the cited pages and requires the Board to draw inferences from those pages. Reliance on another patent's prosecution history as written-description evidence for the '036 patent requires explanation that has not been provided.

Date: October 2, 2026

Respectfully submitted,

/David I. Berl/

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Lead Counsel for Patent Owner

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

The undersigned hereby certifies that on October 2, 2026, I caused a true and correct copy of Patent Owner's Objections to Evidence to be served via e-mail on the following:

| <b>Name</b>         | <b>E-Mail Address</b>   |
|---------------------|-------------------------|
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Date: October 2, 2026

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