[Your Name]
[Your Title]
[Your Company]
[Street Address, City, State ZIP]

May 14, 2026

[Opposing Counsel Name]
[Firm Name]
[Address]

Re: U.S. Patent No. 12168036 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12168036 (the "12168036 Patent"). After preliminary review, we have substantial concerns about the validity, enforceability, and scope of the asserted claims, summarized below. We reserve all rights and defenses.

1. Subject Patent — Summary

Summary of U.S. Patent 12,168,036
A review of U.S. Patent 12,168,036 indicates the patent is the subject of a Post-Grant Review (PGR) proceeding before the Patent Trial and Appeal Board (PTAB) as of April 2, 2026. A search for related 2026 dockets at the Court of Appeals for the Federal Circuit (CAFC) yielded no results.
Title: Methods for treating angiogenic eye disorders with high doses of VEGF receptor fusion proteins
Assignee: Regeneron Pharmaceuticals, Inc.
Inventors: Kenneth S. Graham, Saurabh Wadhwa
Filing Date: July 23, 2021
Issue Date: December 17, 2024
Abstract: The present invention provides ophthalmic formulations having high concentrations of vascular endothelial growth…

2. Validity Concerns under 35 U.S.C. § 102 — Prior Art

We have identified prior-art references that, in our preliminary view, anticipate one or more asserted claims of the 12168036 Patent:

Analysis of Prior Art Cited in U.S. Patent 12,168,036
This analysis details the prior art references cited during the prosecution of U.S. Patent 12,168,036. For each reference, a brief description is provided along with an assessment of which claims it could potentially anticipate under 35 U.S.C. § 102. Anticipation under § 102 requires that a single prior art reference discloses each and every element of a claimed invention.
A review of the patent file wrapper indicates the following documents were cited by the examiner as relevant prior art.
U.S. Patent Publications
1. US 2019/0343918 A1
• Full Citation: United States Patent Application Publication No. 2019/0343918 A1.
• Publication Date: November 14, 2019.
• Filing Date: May 9, 2019.
• Brief Description: This patent application, from the same inventors and assignee (Regeneron), discloses high-concentration formulations of VEGF receptor fusion proteins, including aflibercept. It describes formulations with varying concentrations of aflibercept (e.g., 80 mg/mL, 140 mg/mL, 150 mg/mL), buffers (including histidine and phosphate),…

3. Obviousness under 35 U.S.C. § 103

Independent of § 102, we believe the asserted claims are obvious in view of combinations of prior art that a person having ordinary skill in the art would have been motivated to combine:

Analysis of Obviousness under 35 U.S.C. § 103 for U.S. Patent 12,168,036
This analysis evaluates whether the claimed invention in U.S. Patent 12,168,036 would have been obvious to a Person Having Ordinary Skill in the Art (PHOSITA) at the time of the invention. An invention is considered obvious if the differences between the invention and the prior art are such that the subject matter as a whole would have been obvious to a PHOSITA.
Definition of a Person Having Ordinary Skill in the Art (PHOSITA)
A PHOSITA in the context of this patent would be a pharmaceutical scientist, biochemist, or chemical engineer. This individual would possess a master's degree or Ph.D. in a relevant field and have several years of experience in the development of liquid biologic formulations, particularly high-concentration monoclonal antibodies or therapeutic fusion proteins. The PHOSITA would be knowledgeable about protein stabilization, viscosity reduction, buffer systems, and the specific requirements and challenges of formulations intended for intravitreal administration.
Analysis of Independent…

4. Litigation History of the Patent

Public records reflect that the 12168036 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

• Alvotech v. Regeneron Pharmaceuticals, Inc. — PGR2025-00085 · Patent Trial and Appeal Board (PTAB) · Pending - Instituted
• Biocon Biologics, Inc. et al. v. Regeneron Pharmaceuticals, Inc. — PGR2026-00039 · Patent Trial and Appeal Board (PTAB) · filed 2026-04-02 · Pending

5. Request

In light of the foregoing, we request that your client (i) provide a detailed claim chart identifying each accused product or service and mapping every limitation of each asserted claim, (ii) identify any prior art known to your client, including any references cited during prosecution or reexamination, and (iii) substantiate the basis for any damages or licensing demand. We are prepared to discuss the matter further once we have received and reviewed the foregoing.

Sincerely,

[Your Name]