

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION**

IN RE: AFLIBERCEPT PATENT LITIGATION

MDL No. 1:24-md-3103-TSK

THIS DOCUMENT RELATES TO:

***Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*,**

Case No. 1:24-cv-39-TSK

Case No. 1:25-cv-74-TSK

**STIPULATION AND ORDER REGARDING
NARROWING OF CLAIMS AND INVALIDITY DEFENSES**

Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) has brought patent infringement actions against Defendant Amgen Inc.’s (“Amgen”) PAVBLU™ product, its biosimilar version of Regeneron’s EYLEA® product. On April 11, 2024, the Judicial Panel on Multi-District Litigation (JPML) entered an order centralizing the cases concerning 2 mg aflibercept biosimilar products in this Court. Dkt. 1. Amgen is the only Defendant remaining in the MDL.¹ The Court entered a Scheduling Order in this MDL on September 29, 2025. ECF No. 663. The Scheduling Order required “the parties to meet and confer to agree on the narrowing of infringement claims and invalidity theories and to submit to the Court a joint proposed infringement and invalidity narrowing schedule by April 29, 2026.” *Id.* at 2. The parties have conferred and jointly stipulate herein to the following proposal for mutual narrowing of claims and invalidity defenses.

IT IS THEREFORE STIPULATED AND AGREED that:

¹ The following actions in this MDL have been terminated: *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, No. 22-cv-61 (N.D. W. Va. terminated Apr. 22, 2025); *Regeneron Pharms., Inc. v. Sandoz Inc.*, No. 24-cv-85 (N.D. W. Va. terminated Sept. 9, 2025); *Regeneron Pharms., Inc. v. Formycon AG*, No. 23-cv-97 (N.D. W. Va. terminated Sept. 29, 2025); *Regeneron Pharms., Inc. v. Celltrion, Inc.*, No. 23-cv-89 (N.D. W. Va. terminated Oct. 21, 2025); *Regeneron Pharms., Inc. v. Celltrion, Inc.*, No. 24-cv-53 (N.D. W. Va. terminated Oct. 21, 2025); *Regeneron Pharms., Inc. v. Samsung Bioepis Co., Ltd.*, No. 24-cv-94 and No. 24-cv-106 (N.D. W. Va. terminated Feb. 12, 2026).

(1) No later than May 22, 2026, Regeneron shall select and identify to Amgen no more than 6 patents (the “Selected Patents”) from 3 patent families and 30 total claims (the “Selected Claims”).

(2) No later than June 26, 2026, Amgen shall select and identify to Regeneron no more than eight invalidity defenses (the “Selected Invalidity Defenses”) for any one Selected Claim.²

For clarity, the number of Selected Invalidity Defenses shall be computed as follows:

- Each term alleged to be indefinite in a claim is one defense;
- An allegation of invalidity under 35 U.S.C. § 112(a) or 35 U.S.C. § 112, first paragraph (pre-AIA) for lack of written description is one defense;
- An allegation of invalidity under 35 U.S.C. § 112(a) or 35 U.S.C. § 112, first paragraph (pre-AIA) for lack of enablement is one defense;
- Each alleged anticipatory reference/reference claim/sale/use is one defense; and
- Each alleged obviousness combination or double patenting combination is one defense.

For purposes of counting obviousness and double-patenting combinations, a single primary reference with any number of secondary references (up to four secondary references) shall count as one defense. For example, the combination of Reference A, Reference B, Reference C, Reference D, and/or Reference E shall count as one defense.

The Selected Invalidity Defenses shall be identified and limited without prejudice to Amgen’s right to include or address background references related to the state of the art, including references evidencing the knowledge of a person of ordinary skill in the art. Such references shall

² A Selected Invalidity Defense may be modified or amended upon a showing of good cause, including but not limited to the Court’s claim construction order, discovery produced by Plaintiff during the course of the litigation relating to an invalidity defense, or an allegation by Plaintiff regarding the priority date of a patent.

not count towards the limit. Amgen may not rely on such “background” references to establish that any element of the Selected Claim was expressly disclosed in the prior art. Reliance on a statement made, or reference presented by, the patent applicant acknowledging that something was known or conventional (i.e., applicant admitted prior art) does not count towards the limit. Additionally, Amgen’s selection of invalidity defenses does not prohibit it from asserting additional defenses, such as non-infringement and unenforceability.

(3) No later than two weeks after the close of expert discovery, Regeneron shall select and identify to Amgen no more than 3 patents (the “Second Selected Patents”) and 9 total claims to assert (the “Second Selected Claims”).

(4) No later than two weeks after Regeneron selects and identifies the Second Selected Patents and Second Selected Claims, Amgen shall select and identify to Regeneron no more than three invalidity defenses (the “Second Selected Invalidity Defenses”) for any one Second Selected Claim. The number of Second Selected Invalidity Defenses shall be computed as set forth in Paragraph 2.

(5) The deadline for the parties to submit dispositive motions (if permitted) shall be modified to two weeks after Amgen identifies the Second Selected Invalidity Defenses.

It is so **ORDERED**.



Thomas S. Kleeh, Chief Judge
Northern District of West Virginia

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