

EXHIBIT A

**BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION**

In re Aflibercept Patent Litigation

MDL No. _____

**MOTION OF PLAINTIFF FOR TRANSFER OF ACTION TO THE
NORTHERN DISTRICT OF WEST VIRGINIA PURSUANT TO 28 U.S.C. § 1407
FOR COORDINATED PRETRIAL PROCEEDINGS**

Regeneron Pharmaceuticals, Inc. (“Regeneron”), by and through undersigned counsel, respectfully moves the Judicial Panel on Multidistrict Litigation to enter an order pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, transferring *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, C.A. No. 2:24-cv-00264, currently pending in the United States District Court for the Central District of California (judge not yet assigned), to Chief Judge Thomas S. Kleeh in the United States District Court for the Northern District of West Virginia, for coordinated pretrial proceedings with the five cases filed by Regeneron that are already pending before Chief Judge Kleeh in the Northern District of West Virginia.

Transfer for pretrial coordination is proper and necessary for the following reasons, as set forth more fully in the accompanying memorandum:

1. Regeneron is the Plaintiff in six actions for patent infringement brought under the patent laws of the United States, Title 35, United States Code, against six defendants:¹

- *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. and Biocon Biologics Inc.*, C.A. No. 1:22-cv-00061 (N.D. W. Va.) (Kleeh, C.J.)

¹ Mylan Pharmaceuticals Inc. (“Mylan”); Biocon Biologics Inc. (“Biocon”); Celltrion, Inc. (“Celltrion”); Formycon AG (“Formycon”); Samsung Bioepis Co. Ltd. (“Samsung”); and Amgen Inc. (“Amgen”) (collectively, “Defendants”).

- *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*,
C.A. No. 1:23-cv-00089 (N.D. W. Va.) (Kleeh, C.J.)
- *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*,
C.A. No. 1:23-cv-00094 (N.D. W. Va.) (Kleeh, C.J.)
- *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*,
C.A. No. 1:23-cv-00106 (N.D. W. Va.) (Kleeh, C.J.)
- *Regeneron Pharmaceuticals, Inc. v. Formycon AG*,
C.A. No. 1:23-cv-00097 (N.D. W. Va.) (Kleeh, C.J.)
- *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*,
C.A. No. 2:24-cv-00264 (C.D. Cal.) (judge not yet assigned)

This motion seeks coordination of these six actions by transferring the *Amgen* action to West Virginia.

2. Five of the six above-listed actions are pending before Chief Judge Kleeh in the Northern District of West Virginia.

3. In the sixth action, Regeneron sued Amgen Inc. in the Central District of California (the “Amgen Action”); that case has not yet been assigned to a judge.

4. All six actions arise out of Defendants’ filings of abbreviated Biologics License Applications (“aBLAs”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, or import biosimilar versions of Regeneron’s Eylea® (aflibercept) product, prior to the expiration of patents owned by Regeneron. Each action involves numerous asserted patents, 13 of which overlap across all six actions: U.S. Patent Nos. 9,222,106; 9,254,338; 9,816,110; 10,130,681; 10,415,055; 10,464,992; 10,669,594; 10,888,601; 11,066,458; 11,084,865; 11,104,715; 11,253,572; and 11,306,135 (the “patents-in-suit”).

5. Each Defendant’s submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e). Each Defendant has indicated that it disputes the validity and/or

infringement of all asserted patents and that it does not intend to await patent expiry to commercialize its biosimilar product. Pursuant to 42 U.S.C. § 262(k)(7)(A), Defendants' aBLAs may be approved as soon as Eylea's regulatory exclusivity expires on May 18, 2024.

6. Regeneron filed the first of the above-listed actions, *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. and Biocon Biologics Inc.* (the "Mylan Action"), in August 2022, after the FDA accepted Mylan's aBLA filing and the parties completed the pre-suit requirements set forth in 42 U.S.C. § 262(l). In June 2023, Chief Judge Kleeh presided over a two-week bench trial involving the infringement and validity of three of Regeneron's patents-in-suit. The Court issued its post-trial decision on December 27, 2023, finding that one of Regeneron's patents-in-suit is valid and infringed by Mylan and Biocon.

7. Regeneron filed suits against Celltrion, Formycon, and Samsung in the Northern District of West Virginia in November 2023 after each sent notice letters to Regeneron indicating that they would begin marketing and selling their respective biosimilar products upon receiving approval from the FDA. 42 U.S.C. § 262(l)(8)(A). On December 27, 2023, Regeneron filed a second suit against Samsung pursuant to 42 U.S.C. § 262(l)(6). On January 10, 2024, Regeneron also filed a suit in the Central District of California against Amgen pursuant to 42 U.S.C. § 262(l)(6).

8. All of the above-listed actions therefore involve the same core issue: whether, by seeking approval of its Eylea biosimilar product, the Defendant has infringed and/or will infringe any valid claim of Regeneron's asserted patents.

9. The above-listed actions present numerous common issues of fact and law, including without limitation the technologies underlying the patents-in-suit; the prosecution histories of the patents-in-suit; the proper construction of claim terms in the patents-in-suit; the

scope and content of the prior art; and any secondary indicia of non-obviousness associated with the products embodying the patents-in-suit. The above-listed actions also present common issues of fact and law with respect to issues of remedies, including injunctive relief.

10. All of the above-listed actions except for the Mylan Action are in their earliest stages. As of the filing of this motion, in all the actions other than the Mylan Action, only a single scheduling conference has occurred, discovery is just beginning, and no substantive orders have issued. On January 9, 2024, Chief Judge Kleeh issued an Order scheduling preliminary injunction proceedings in the Celltrion, Formycon, and Samsung Actions, culminating in a combined preliminary injunction hearing on May 2, 2024. That Order is attached as Exhibit 7 to this motion.

11. In the Mylan Action, Regeneron provided extensive discovery as to six patents from three patent families, and the Court issued a claim construction opinion on 12 claim terms of the six patents and a decision following a two-week trial on 12 asserted claims from three of the patents-in-suit. Four of the six patents construed by the Court in the Mylan Action are asserted in all six actions.

12. Regeneron intends to seek an injunction against each of the Defendants to prevent them from marketing their proposed biosimilars before patent expiry in each of the above-listed actions. As mentioned above, a preliminary injunction hearing has been scheduled for May 2, 2024, in four of the cases currently pending before Chief Judge Kleeh. Ex. 7. As the Mylan Action has already proceeded to trial, Regeneron will seek permanent injunctive relief from Chief Judge Kleeh in that case.

13. Transfer and coordination of the above-listed action is necessary to: (a) eliminate the potential for inconsistent rulings on pretrial motions, including but not limited to any claim construction rulings; (b) eliminate the burden of duplicative discovery on common issues; (c) avoid

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