BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re Aflibercept Patent Litigation	MDL No. _____

MISCELLANEOUS MOTION TO EXPEDITE REVIEW OF PLAINTIFF'S MOTION TO TRANSFER TO THE NORTHERN DISTRICT OF WEST VIRGINIA PURSUANT TO 28 U.S.C. § 1407

Pursuant to Panel Rule 6.3, Regeneron Pharmaceuticals, Inc. ("Regeneron") respectfully requests that the Panel expedite briefing and resolution of its application to transfer *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, C.A. No. 1:24-cv-00264 (the "Amgen Action"), currently pending in 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 other cases now pending before Chief Judge Kleeh. J.P.M.L. Rule 6.3 ("Motions for miscellaneous relief include . . . requests for . . . expedited consideration of any motion.").[1]

The need for expedited consideration arises from the urgency of preliminary injunction proceedings now underway in West Virginia. Regeneron intends to file motions for preliminary injunctions in the Amgen Action and in four of the five Regeneron cases pending before Chief Judge Kleeh in West Virginia, relying on common facts across all of the cases.[2] On January 9,

[1] Regeneron seeks to coordinate the Amgen Action with five cases filed by Regeneron currently pending in the Northern District of West Virginia: *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.); *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.).

[2] As explained below, in one of the five cases pending in West Virginia, against Mylan and Biocon, the Court recently issued a post-trial decision relating to patents asserted in the Amgen

2024, Chief Judge Kleeh entered a schedule for those proceedings (as well as for dispositive motion briefing) in West Virginia. That schedule, attached hereto, is designed to achieve completion of preliminary injunction proceedings by May 17, 2024, before FDA regulatory exclusivity for Regeneron's Eylea product expires. The schedule requires exchanges of documents beginning in January, preliminary injunction briefing beginning February 22, preliminary injunction oppositions due on March 21, and ultimately a preliminary injunction hearing on May 2. Ex. 7. Judicial efficiency dictates having a single court preside over the preliminary injunction proceedings against Samsung, Celltrion, Formycon, and Amgen, which will involve overlapping patents and common issues of patent validity, irreparable harm, balance of hardships, and public interest. Because substantial preliminary injunction discovery and briefing will occur under the West Virginia schedule before the Panel's March 25 hearing date, absent expedited review, transfer to West Virginia could result in the Court having to supervise and adjudicate multiple, serial preliminary injunction proceedings—first against the West Virginia Defendants, and then again against Amgen. *See In re Kerydin (Tavaborole) Topical Sol. 5% Pat. Litig.*, 366 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019) (noting "the need for swift progress in litigation involving the potential entry of generic drugs into the market" as a major reason for centralization of patent infringement actions).

As Regeneron's motion for transfer details, the Amgen Action and the five actions pending in West Virginia are similar procedurally and factually. In each action, the Defendant has filed an abbreviated Biologic License Application ("aBLA") seeking FDA approval to market "biosimilar"

Action and the other cases pending in West Virginia. In the case against Mylan and Biocon, Regeneron intends to file a motion for permanent injunction, which will raise the same issues of irreparable harm, balance of hardships, and public interest as the preliminary injunction motions in the Amgen Action and the four other cases pending in West Virginia. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

versions of Regeneron's flagship biopharmaceutical product, Eylea® (aflibercept). In each lawsuit against each Defendant, Regeneron has alleged infringement of an overlapping set of patents based on the filing of the Defendants' aBLAs and their plans to make, use, and sell their biosimilar versions of Eylea. Each Defendant has asserted, in pre-suit exchanges under the governing statute, that it believes that Regeneron's asserted patents are invalid and/or not infringed, thereby permitting the biosimilar applicant to commercialize its product before the patents expire. Whether through formal notice or through attorney communications, each of the Defendants has indicated an intent to market its biosimilar product upon FDA approval of its application, following expiration of Regeneron's regulatory exclusivity on May 18, 2024, unless enjoined by a court. Critically, each Defendant intends to do so without regard to Regeneron's extensive portfolio of patents covering its Eylea product and related technologies.

Each case also involves a request by Regeneron for injunctive relief. Five of the six pending cases, including the Amgen Action, were filed within the past three months. Given the limited time before the May 2024 expiration of Eylea's regulatory exclusivity (after which the FDA may approve Defendants' applications for biosimilar versions of Eylea), Regeneron is seeking preliminary injunctive relief in each of those cases. The action against Defendants Mylan and Biocon ("the Mylan Action") is situated differently. The complaint in that case was filed in mid-2022 based on Mylan's earlier aBLA filing date, and Regeneron sought and obtained an expedited litigation schedule, culminating in a two-week bench trial before Chief Judge Kleeh in June 2023. On December 27, 2023, Chief Judge Kleeh issued a detailed post-trial opinion finding that one of Regeneron's patents—a patent asserted in all subsequent cases against all other Defendants—was valid and infringed. Regeneron thus intends to seek permanent injunctive relief in the Mylan Action, and that proceeding will address the same issues of irreparable harm, balance

of hardships, and public interest as the imminent preliminary injunction proceedings against the four other Defendants.

Based on the urgency of the five actions involving preliminary injunction proceedings—including the Amgen Action—Regeneron respectfully requests that the Panel expedite consideration of Regeneron's motion to transfer the Amgen Action to Chief Judge Kleeh of the Northern District of West Virginia, who already presided over a two-week bench trial involving one set of Defendants and who is presiding over three of the four actions in which Regeneron is seeking preliminary injunctive relief. Regeneron's preliminary injunction motions against these Defendants will be based on a range of common facts—including common asserted patents, claim constructions, infringement and invalidity theories, the public interest in injunctive relief, and Regeneron's irreparable harm. *See Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1363–64 (Fed. Cir. 2017). Rapid resolution of the motion to transfer the Amgen Action to the Northern District of West Virginia is therefore essential to avoid unnecessary waste of party and judicial resources and the risk of inconsistent decisions.

Indeed, absent expedited review, Regeneron and the courts presiding over these actions may have to litigate preliminary injunction motions twice, given that the injunction proceedings, including discovery and the principal briefing, against the West Virginia Defendants will occur before the Panel's March 25 hearing date. Ex. 7.

Due to the time-sensitive nature of the motion and the relief sought, Regeneron is willing to waive oral argument in order to make expedited consideration more feasible.[3] *See, e.g.*, *In re FY 2022 Adjustment of Status Delay Litig.*, 621 F. Supp. 3d 1351, 1352 n.2 (J.P.M.L. 2022)

[3] If expedited review is denied, however, Regeneron intends to request oral argument pursuant to Panel Rule 11.1(b).

(granting expedited consideration without oral argument where relief sought was highly time-sensitive). Regeneron is also willing to undertake a briefing schedule that the Panel finds appropriate, including in the time required for the case to be heard at the Panel's January 25 hearing.

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