

**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.,

No. 1:23-cv-97-TSK

Plaintiff,

v.

FORMYCON AG,

Defendant.

**DEFENDANT FORMYCON AG'S MOTION TO PARTIALLY ADOPT AND JOIN
SAMSUNG BIOEPIS, CO., LTD.'S MOTION FOR ENTRY OF SCHEDULING ORDER
PURSUANT TO RULE 16 OR, IN THE ALTERNATIVE, A STATUS CONFERENCE**

Defendant Formycon AG (“Formycon”), through its undersigned counsel, hereby moves to partially join Defendant Samsung Bioepis Co., Ltd.’s motion for entry of a scheduling order pursuant to Rule 16 or, in the alternative, for scheduling a status conference. (24-md-3103, Dkt. No. 478.) Specifically, Formycon moves to join Samsung Bioepis Co., Ltd.’s request for a status conference.

Regeneron is wrong that discussion of any schedule should wait for all defendants to line up to the same procedural posture before recognizing the “efficiency gains for which this MDL was instituted.” (*Id.*, Dkt. No. 483 at 1.) MDLs may offer efficiency gains by transferring similar actions to the same court, but those efficiencies do not require all cases comprising in an MDL move in lock-step along the same schedule. That is especially true here given that the Judicial Panel on Multidistrict Litigation recognized that later filed cases “may trail those in the [earlier filed] West Virginia actions” and “still . . . provide efficiencies for the parties and preserve judicial resources.” (*Id.*, Dkt. No. 1 at 3.) The Panel thus granted centralization on the expectation that transfer would not delay the earlier filed actions. (*Id.*) In other instances where a Panel expects an MDL might delay proceedings already underway, the Panel denies transfer requests. *See, e.g., In re Atrium Med. Corp. ProLite & ProLoop Hernia Mesh Prods. Liab. Litig.*, 600 F. Supp. 3d 1340 (J.P.M.L. 2022) (denying motion for MDL where benefits of centralization did not outweigh the fact that it would delay progress of some actions).

Courts managing MDLs regularly move constituent cases along on separate tracks. (*See, e.g., In re EpiPen Mktg. Litig.*, No. 17-MD-27885, 2019 WL 294803 at *6 (D. Kan. Jan 23, 2019) (“Delay also concerns the court. That is why it has ordered the cases to proceed on separate litigation tracks.”); *In re Pork Antitrust Litig.*, 2021 WL 5310590 at *4 (D. Minn. Nov. 14, 2021) (discussing “separate tracks” to “decrease the risk of delay” in consolidated proceedings); *In re Inclusive Access Course Materials Litig.*, 482 F. Supp. 3d 1358, 1359 (J.P.M.L. 2020) (“The transferee judge can use

separate tracks or other appropriate pretrial techniques to address any issues specific to [an individual case].”).) As an example, the Honorable Judge O’Hearn of the District of New Jersey is currently managing an MDL of five cases in which biosimilars seek to market Amgen’s denosumab products.¹ A timeline of those proceedings is below.²



In November 2024, Judge O’Hearn scheduled the Celltrion case for an expedited trial in April 2025. At the same time Judge O’Hearn was also managing the SB case and Amgen’s related proceedings involving its claims against Celltrion.³ Judge O’Hearn is now handling cases against SB, Fresenius Kabi, and Accord. In contrast to the SB case, which is poised to move towards preliminary injunction proceedings or an expedited trial, the Fresenius Kabi and Accord matters are in relatively

¹ Judge O’Hearn held oral argument on Amgen’s preliminary injunction motion against Sandoz, and the parties settled before the scheduled hearing for the court to deliver its opinion on the motion. (23-cv-2406, Dkt. No. 437.) The court continues to handle ancillary matters on the Sandoz docket.

² The parties to the denosumab litigations in the District of New Jersey are Amgen Inc. and Amgen Manufacturing Ltd. LLC (“Amgen”); Sandoz Inc., Sandoz GmbH, Lek Pharmaceuticals D.D., Novartis Pharmaceuticals Production D.O.O., and Novartis AG (“Sandoz”) (23-cv-2406); Celltrion, Inc. and Celltrion USA, Inc. (“Celltrion”) (24-cv-6497); Samsung Bioepis Co., Ltd. and Samsung Biologics Co., Ltd. (“SB”) (24-cv-8417); Fresenius Kabi Austria GmbH, Fresenius Kabi Deutschland GmbH, Fresenius Kabi SwissBioSim GmbH, and Fresenius Kabi USA, LLC (“Fresenius Kabi”) (25-cv-1080); and Accord BioPharma, Accord Healthcare, Inc., and Intas Pharmaceuticals Limited (“Accord”) (25-cv-1305).

³ The related actions before Judge O’Hearn are *Amgen Inc. v. Celltrion USA, Inc.* (24-cv-9052) (seeking discovery from Celltrion USA, Inc. pursuant to 28 U.S.C. § 1782) and *In re Subpoena to Fujifilm Irvine Scientific* (24-cv-8830) (seeking third-party discovery from Celltrion’s media supplier). Amgen and Celltrion recently settled on January 23, 2025, (24-cv-6497, Dkt. No. 310), but ancillary matters remain pending before the court.

nascent stages. The same approach in the denosumab MDL is applicable to Regeneron's cases against the aflibercept biosimilars—earlier filed cases that are more developed should proceed on a different track than the later filed cases.

Proceeding on alternate tracks is particularly appropriate for biosimilar competitors, as they have different business considerations and product launch dates that necessitate different paths to resolution. For example, SB identifies commercial harm as a basis for speedy resolution of Regeneron's claims against it (24-md-3101, Dkt. No. 478 at 1) while Sandoz appears in no rush, as reflected by the four agreed extensions to respond to initial pleadings filed by the parties since the case began over five months ago. (24-cv-85, Dkt. Nos. 15, 41, 55, 58.) And more aflibercept litigations are likely on the horizon—just this week Alvotech announced that FDA accepted its BLA for an EYLEA® biosimilar.⁴ Simply put, forcing all biosimilars to adhere to the same schedule prejudices earlier BLA submitters by indefinitely delaying final resolution of Regeneron's claims against them.

Just as a quarterback must be prepared to read different teams' zone and man coverage, Regeneron cannot sit on the sideline waiting for every defense to look the same. Here, Formycon agrees with SB that a schedule should issue for some defendants. The contours of that schedule, including the proper scope of discovery and case narrowing deadlines, are best negotiated once the parties discuss the Court's preferences and expectations for advancing these cases during a scheduling conference.

⁴ <https://investors.alvotech.com/news-releases/news-release-details/alvotech-and-teva-announce-filing-acceptance-us-biologics-0>. Other anticipated aflibercept biosimilars include Rophibio and Bora Pharmaceuticals' RBS-001 and SamChunDang and Fresenius Kabi's SCD-411. See <https://www.taiwan-healthcare.org/en/news-detail?id=0sh1xgg2n9nggra3>; <https://www.pearceip.law/2024/03/25/sam-chun-dang-to-distribute-eylea-aflibercept-biosimilar-in-nine-european-countries/>.

Dated: February 21, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned attorney hereby certifies that on February 21, 2025, I caused a true and correct copy of the foregoing *Defendant Formycon AG's Motion To Partially Adopt and Join Samsung Biopeis, Co., Ltd.'s Motion for Entry of Scheduling Order Pursuant to Rule 16 or, in the Alternative, A Status Conference* to be filed via the Court's CM/ECF electronic filing system, thereby sending notice of the filing to all CM/ECF-registered counsel of record for Plaintiff.

/s/ M. David Griffith, Jr.
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