

**THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

AMGEN, INC., et al.,

Plaintiffs,

v.

SAMSUNG BIOEPIS, CO., et al.,

Defendants.

Civil No. 24-8417 (CPO/EAP)

SCHEDULING ORDER

This Scheduling Order confirms the directives given to counsel at the initial scheduling conference held pursuant to Federal Rule of Civil Procedure 16 on **November 6, 2024**; and the Court noting the following appearances: **Marc D. Haefner, Esquire, David L. Anderson, Esquire, Steven J. Horowitz, Esquire, Lauren Katzeff, Esquire, Michael D. Hatcher, Esquire, and C. Nichole Gifford, Esquire**, appearing on behalf of Plaintiffs; and **William C. Baton, Esquire, Jeanna M. Wacker, Esquire, Sam Kwon, Esquire, Ashley Ross, Esquire**, appearing on behalf of Defendants; and for good cause shown;

IT IS this 6th day of November 2026, hereby ORDERED:

1. Defendants shall submit for *in camera* review Samsung Bioepis Co., Ltd.'s launch plans to the Honorable Christine P. O'Hearn, U.S.D.J. as follows:
 - a. No later than **December 6, 2024**, Defendants shall submit a specific and detailed letter setting forth: (i) Defendant Samsung Bioepis Co., Ltd.'s launch plans; (ii) all of the critical steps in the supply chain; and (iii) Defendants' status within that chain.
 - b. Within **seven (7) days** of any change in launch plans or Defendant Samsung Bioepis Co., Ltd.'s receipt of any correspondence from the FDA that may affect launch plans, Defendants shall inform Judge O'Hearn and provide any relevant FDA correspondence.
2. Defendants shall produce all FDA correspondence related to Samsung Bioepis Co., Ltd.'s BLA to Plaintiffs' counsel, as follows:
 - a. No later than **December 6, 2024**, Defendants shall produce all past FDA correspondence.
 - b. Within **fourteen (14) days** of receipt of any future correspondence with the FDA, Defendants shall produce such correspondence to Plaintiffs' counsel.

3. Defendant Samsung Biologics Co., Ltd.'s request to stay discovery pending the outcome of its prospective motion to dismiss is **DENIED WITHOUT PREJUDICE**.

4. No later than **November 13, 2024**, Plaintiffs shall respond to Defendants' proposed ESI order.

5. No later than **November 20, 2024**, Defendant Samsung Biologics Co., Ltd. shall inform the Court and Plaintiffs whether it intends to produce the affidavits and exhibits referenced in its pre-motion conference letter, ECF No. 52, at 2 n.1, in exchange for narrowed jurisdictional discovery.

6. No later than **November 20, 2024**, Defendant Samsung Bioepis Co. Ltd. shall inform the Court and Plaintiffs whether it will agree to a consent injunction not to launch its biosimilar prior to May 31, 2025.

7. By no later than **November 27, 2024**, the parties shall submit to the Court a joint report, either by filing on the docket under seal or by email to [njdnep_pascal@njd.uscourts.gov](mailto:njdnef_pascal@njd.uscourts.gov), stating whether they agree to participate in private mediation.

8. No later than **November 27, 2024**, the parties shall meet and confer regarding a proposed case management schedule, including but not limited to, the timeline for reciprocal discovery; the breadth of reciprocal discovery; jurisdictional discovery, if needed; and a date by which Samsung Biologics Co., Ltd. should respond to Amgen's outstanding requests for the production of documents and interrogatories. No later than **December 4, 2024**, the parties shall submit a joint proposed case management schedule to the Court, noting any areas of disagreement. If necessary, the Court will schedule a conference with the parties upon receipt.

9. Any application for an extension of time beyond the deadlines set herein shall be made prior to expiration of the period sought to be extended and shall disclose in the application all such extensions previously obtained, the precise reasons necessitating the application showing good cause under FED. R. CIV. P. 16(b), and whether adversary counsel consent to the application. The scheduling deadlines set herein will not be extended unless good cause is shown. All applications regarding motions returnable before a District Judge shall be presented to the District Judge.

**THE FAILURE OF A PARTY OR ATTORNEY TO OBEY THIS ORDER
MAY RESULT IN IMPOSITION OF SANCTIONS UNDER FED. R. CIV. P. 16(f).**

s/Elizabeth A. Pascal
ELIZABETH A. PASCAL
United States Magistrate Judge

cc: Hon. Christine P. O'Hearn, U.S.D.J.