

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CELLTRION, INC.,

Defendant.

Civil Action No. 1:23-cv-89-TSK

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

SAMSUNG BIOEPIS, CO., LTD.,

Defendant.

Civil Action No. 1:23-cv-94-TSK

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

SAMSUNG BIOEPIS, CO., LTD.,

Defendant.

Civil Action No. 1:23-cv-106-TSK

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

FORMYCON AG,

Civil Action No. 1:23-cv-97-TSK

Defendant.

### **CASE MANAGEMENT AND SCHEDULING ORDER**

Pursuant to Federal Rules of Civil Procedure 16(b) and 26(f) and the Local Rules of Civil Procedure and 42 U.S.C. § 262(l)(8)(C), the Court enters the following Case Management and Scheduling Order.

WHEREAS Plaintiff Regeneron Pharmaceuticals, Inc. initiated this civil action with the filing of a Complaint against each of Defendants Samsung Bioepis Co., Ltd. (“Samsung”), Celltrion, Inc. (“Celltrion”), and Formycon AG (“Formycon”) (the “Actions”);

WHEREAS the United States Food and Drug Administration is currently reviewing each of Defendants’ Biologic License Applications seeking approval to market a biosimilar version of Regeneron’s aflibercept (Defendant’s “Aflibercept aBLA”);

WHEREAS Regeneron commits not to file a motion for preliminary injunction on any patents other than those identified pursuant to the schedule below;

WHEREAS the Parties shall reasonably cooperate to expedite these proceedings and facilitate the Court’s resolution of the Parties’ disputes.

<b>Event</b>	<b>Deadline</b>
Regeneron delivers targeted requests for production	December 22, 2023 (completed)
Regeneron identifies no more than eight patents that may be included in a Motion for	Within two business days of the entry of this order.

Preliminary Injunction; Defendants deliver targeted requests for production	
Regeneron makes initial production of documents	Within one business day of agreement by counsel for a Defendant to maintain such documents on an outside-attorney's-eyes-only basis until a protective order has been entered.
Defendant's deadline to answer or otherwise respond to the Complaint, e.g., by filing a motion for lack of personal jurisdiction and/or improper venue	January 12, 2024
Defendant produces documents responsive to Regeneron's requests	January 26, 2024
Regeneron completes production of documents related to preliminary injunction, including documents related to patents it may assert in preliminary injunction motion	February 2, 2024
Regeneron identifies patents it may assert in preliminary injunction motion	February 2, 2024
Regeneron to file opposition to any motion for lack of personal jurisdiction and/or improper venue	February 19, 2024
Regeneron to file motion for preliminary injunction and single supportive memorandum against all Defendants in case Nos. 1:23-cv-89-TSK, 1:23-cv-94-TSK, 1:23-cv-97-TSK, and 1:23-cv-106-TSK.	February 22, 2024
Defendant may file a reply ISO motion for personal jurisdiction and/or improper venue	March 6, 2024
Depositions of any Regeneron declarants <sup>1</sup> complete	March 13, 2024
Defendants in case Nos. 1:23-cv-89-TSK, 1:23-cv-94-TSK, 1:23-cv-97-TSK, and 1:23-cv-106-TSK file single opposition to motion for preliminary injunction	March 21, 2024

<sup>1</sup> The parties shall present any declarant for deposition in the continental United States.

Deposition of Defendants' declarants complete	April 10, 2024
Regeneron files single reply ISO preliminary injunction	April 18, 2024
Proposed hearing on Regeneron's motion for preliminary injunction	_____ [week of April 29, 2024]
In-person status conference with lead counsel ahead of May 18, 2024 expiration of regulatory exclusivity	May 13, 2024

To the extent that the Parties have any discovery disputes, such disputes will be resolved on an expedited basis consistent with the principles outlined in 42 U.S.C. § 262(l)(8)(C).

SO ORDERED this \_\_\_\_\_ of January, 2024.

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United States District Judge