

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

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. CELLTRION, INC., Defendant.	Civil Action No. 1:23-cv-00089-TSK
REGENERON PHARMACEUTICALS, INC., Plaintiff, v. SAMSUNG BIOEPIS CO., LTD., Defendant.	Civil Action No. 1:23-cv-00094-TSK
REGENERON PHARMACEUTICALS, INC., Plaintiff, v. FORMYCON AG, Defendant.	Civil Action No. 1:23-cv-00097-TSK
REGENERON PHARMACEUTICALS, INC., Plaintiff, v. SAMSUNG BIOEPIS CO., LTD., Defendant.	Civil Action No. 1:23-cv-00106-TSK

**DEFENDANTS CELLTRION, INC., SAMSUNG BIOEPIS CO., LTD.,
AND FORMYCON AG'S RESPONSE TO PLAINTIFF'S EMERGENCY
MOTION FOR CLARIFICATION OF THE COURT'S JANUARY 9, 2024 ORDER**

Defendants Celltrion, Inc. (“Celltrion”), Samsung Bioepis Co., Ltd. (“SB”), and Formycon AG (“Formycon”) (collectively, “PI Defendants”)¹ jointly submit this response to Plaintiff Regeneron Pharmaceuticals, Inc.’s (“Regeneron”) Emergency Motion for Clarification of the Court’s January 9, 2024 Order. (ECF No. 95 in Case No. 1:23-cv-89, ECF No. 96 in Case No. 1:23-cv-94, ECF No. 80 in Case No. 1:23-cv-97, and ECF No. 77 in Case No. 1:23-cv-106 (“Mot.”).)²

This dispute arises from the Court’s January 9, 2024 Order Setting Briefing Schedule on Motions to Dismiss and Setting Schedule for Preliminary Injunction Proceedings. (ECF No. 61 in 1:23-cv-89, ECF No. 69 in Case No. 1:23-cv-94, ECF No. 45 in Case No. 1:23-cv-97, and ECF No. 40 in Case No. 1:23-cv-106 (“Scheduling Order”).) Under Regeneron’s proposed briefing procedure, its omnibus brief in opposition to the PI Defendants’ motions to dismiss for lack of personal jurisdiction will contain highly confidential information from each PI Defendant, including information relating to their commercialization plans, in unredacted format subject to inspection by each PI Defendant. But each PI Defendant closely guards this highly confidential information, especially with respect to the other PI Defendants, all of whom are direct competitors seeking to launch their own biosimilars of Eylea®. The Court should thus reject Regeneron’s proposal and, instead, direct Regeneron to file its brief under seal for the Court’s review and serve on each PI Defendant a redacted copy of its brief to protect highly confidential information. To the extent Regeneron believes that redaction would frustrate the PI Defendants’ ability to respond, then Regeneron should file separate briefs.

¹ The PI Defendants’ counsel have appeared specially for the limited purpose of contesting jurisdiction and have already filed their respective motions to dismiss pursuant to Fed. R. Civ. P. 12(b)(2). This brief, which is limited to procedural aspects of the case, is being submitted to facilitate early and prompt resolution of the PI Defendants’ jurisdictional challenge.

² In the interest of efficiency, the PI Defendants have filed this identical response in each of their respective actions.

ARGUMENT

Regeneron “requests the Court’s guidance on how to effectuate its order to file an omnibus response” to the PI Defendants’ motions to dismiss for lack of personal jurisdiction “while also referencing Defendants’ confidential information.” (Mot. at 5.) Regeneron asserts that it “proposed a reasonable compromise, which Defendants rejected outright and without providing a counterproposal.” (*Id.*) Regeneron is incorrect on both points. Its proposal is not reasonable—in fact, it would be a violation of the terms of the Protective Order that Regeneron and the PI Defendants have nearly finalized and would unnecessarily expose some of the most commercially sensitive confidential information of each defendant to the others. And the PI Defendants did provide a counterproposal during last Friday’s meet and confer—that Regeneron serve a redacted version of its omnibus response on counsel simultaneously with its under seal filing with this Court. The PI Defendants’ counterproposal is the best way to proceed under the circumstances.

I. Regeneron’s Proposal Would Expose Each PI Defendant’s Highly Confidential Business Information and Violate the Protective Orders That Are Nearly Finalized.

Given the highly confidential nature of this information, Regeneron’s proposal – that outside counsel for each PI Defendant be allowed to view an unredacted omnibus opposition brief – is not acceptable. As the PI Defendants explained to Regeneron during the parties’ February 9, 2024 meet and confer, knowing the commercialization strategy of another defendant would potentially affect the other defendants’ litigation strategy and potentially provide a significant business advantage. The PI Defendants further explained that allowing outside counsel for the PI Defendants to view each other’s confidential or outside-counsel’s-eyes-only (“OCEO”)

information would clearly violate the draft proposed protective orders in each of the PI Defendants' respective actions, which the parties are nearly done negotiating. (*E.g.*, Ex. A.³)

The draft protective orders provide that confidential and OCEO information in each action may be disclosed by the receiving party (here, Regeneron) ***only*** to certain "Qualified Persons," which includes the receiving party's ***own*** outside counsel of record. (*Id.* ¶¶ 9–10.) Unsurprisingly, the draft protective orders do not allow Regeneron to disclose a PI Defendant's confidential or OCEO information to outside counsel for ***other*** PI Defendants in ***different*** cases. After all, this is highly confidential information to each individual PI Defendant.

In fact, the draft protective order that Regeneron proposed to each individual defendant specifically defines "Action" as limited to the action against that individual defendant – *e.g.*, "Action" as to Formycon means ***only*** "the case captioned Regeneron Pharmaceuticals, Inc. v. Formycon AG, Civil Action No. 1:23-cv-00097-TSK, which is currently pending in the Northern District of West Virginia," and not the actions pending against Celltrion or SB. (*Id.* ¶ 1(b).) The draft protective orders further provide: "All Protected Material shall be used solely for ***this Action***, including any appeal(s) therefrom or any remands thereto. Protected Material ***may not be used under any circumstances for a related, separate or foreign action or proceeding***, prosecution of any patent application, patent licensing or for any other purpose." (*Id.* ¶ 6 (emphasis added).)

Despite these provisions, Regeneron proposed submitting each PI Defendant's confidential information in the other actions by filing its omnibus opposition brief and serving an unredacted copy on all outside counsel. Thus, not only would Regeneron's proposal inflict substantial harm

³ Solely for purposes of this response, the draft proposed protective order attached as Exhibit A, which relates to Case No. 1:23-cv-97, accepts all changes and deletes all comments in the latest draft provided by Regeneron. The PI Defendants understand that Regeneron sent substantively identical drafts to each of them during the most recent exchange of drafts.

on the PI Defendants' business interests by needlessly exposing highly confidential business information, it would also violate the protective orders that Regeneron has nearly finished negotiating. The Court should reject Regeneron's proposal on those grounds.

II. The Court Should Adopt the PI Defendants' Counterproposal for Handling Their Highly Confidential Business Information in Regeneron's Omnibus Opposition.

After explaining to Regeneron that its proposal failed to address concerns over confidentiality, in an effort to compromise, the PI Defendants made a simple, easy-to-implement counterproposal for purposes of the PI Defendants' motions to dismiss: that Regeneron serve on each PI Defendant a copy of its omnibus opposition brief redacting confidential and OCEO information from the other PI Defendants simultaneously with Regeneron's filing of its omnibus opposition brief under seal. This proposal respects the PI Defendants' confidentiality interests and the draft proposed protective orders by ensuring that outside counsel for the PI Defendants are not exposed to each other's confidential or OCEO information.

Regeneron should be capable of determining what information to redact from each PI Defendant. Much of that information has already been designated as confidential or OCEO by each of the individual PI Defendants. If Regeneron is unsure whether to redact certain information from a PI Defendant, it can ask each Defendant now whether it considers the information to be confidential and redact it accordingly. Or Regeneron could simply redact *all* information from a given PI Defendant from the versions of the omnibus opposition brief provided to the other PI Defendants (so long as Regeneron does not discuss each PI Defendants' confidential information in a manner that cannot be separated, as discussed further below). Regeneron also has ample time to make these redactions before the February 19, 2024 deadline for its opposition and to provide a redacted copy with its filing. Indeed, this is often done in other jurisdictions.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.