

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

IN RE: AFLIBERCEPT PATENT LITIGATION

Case No. 1:24-md-3103-TSK

**THIS DOCUMENT RELATES TO ALL CASES**

**PLAINTIFF REGENERON PHARMACEUTICAL INC.’S RESPONSE TO  
DEFENDANT AMGEN INC.’S MOTION REQUIRING FILING AND SERVING OF  
REDACTED VERSIONS OF SEALED FILINGS**

Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) hereby responds to the motion filed by Defendant Amgen Inc. (“Amgen”) seeking entry of an order requiring all parties to this multi-district litigation (MDL) to file and serve redacted copies of all documents docketed under seal after June 11, 2024. (ECF No. 164.) Regeneron understands that Defendants Mylan Pharmaceuticals Inc., Biocon Biologics Inc., Samsung Bioepis Co., Ltd., Celltrion, Inc., and Formycon AG do not oppose Amgen’s motion. Regeneron likewise does not oppose entry of an order setting forth a process by which parties to this MDL must provide redacted copies to each other and to the public—to the contrary, Regeneron welcomes such a proposal. Regeneron opposes Amgen’s motion only for two reasons: (1) Amgen’s proposed order omits certain logistical details—namely, a date certain by which Defendants must identify their confidential information in a document before Regeneron is obligated to produce that document to another party; and (2) Amgen’s proposed order does not address important categories of additional documents—namely, deposition transcripts and sealed papers dated *before* June 11, 2024. Regeneron briefly explains these concerns below, and attaches hereto as Exhibit 1 a redline showing its requested changes to Amgen’s proposed order. Regeneron made similar suggestions before Amgen filed its motion; Amgen ignored Regeneron’s concerns and filed its motion without responding to Regeneron’s proposal.

**I. Regeneron Needs Redacted Copies from Defendants Before it Produces Them**

Amgen’s proposed order sets forth procedures by which:

(1) Papers filed under seal in a single member case are to be served on all parties to the MDL in a form that redacts all Defendants' confidential information (ECF No. 164-2, ¶ 2);

(2) Papers filed under seal are to be filed on the public docket in a form redacting all parties' confidential information (ECF No. 164-2, ¶ 3);

(3) Orders, memoranda, opinions or other documents entered by the Court under seal are to be filed on the public docket in a form redacting all parties' confidential information; and (ECF No. 164-2, ¶ 4);

(4) Orders, memoranda, opinions or other documents entered by the Court under seal in a single member case are to be served on all parties to the MDL in a form that redacts all Defendant confidential information, but not Regeneron information (ECF No. 164-2, ¶ 5).

These are salutary goals. Regeneron would like to effectuate them, but must be sure it can meet its obligations under both Amgen's proposal *and* the protective orders in force in each member case. In particular, Regeneron depends on Defendants to identify what information they consider confidential in a given document. Defendants must do this for any document—whether filed by a Defendant or filed by Regeneron or entered by the Court—before Regeneron can serve that document on another party. Amgen's proposed order states only that "is the responsibility of the Defendant whose confidential information is at issue to timely provide redactions to the Party that is required by this Order to file or serve a redacted copy that does not contain any Defendant's confidential information." ECF No. 164-2 at ¶ 6. Regeneron is concerned that this vague "timeliness" requirement will not allow it to meet the deadlines specified in Amgen's proposal.

In particular, paragraphs two and five of Amgen's proposed order require Regeneron to serve on all parties to the MDL a copy of any paper Regeneron files under seal (ECF No. 164-2 at ¶ 2) and any order or other document entered by the Court under seal (ECF No. 164-2 at ¶ 5) in a form that redacts the applicable Defendant's confidential information. After receiving from the Defendant a copy of the document identifying all confidential information it believes should be redacted, Regeneron will need to load the redacted copy into its document system, identify the appropriate confidentiality designation

depending on the presence of Regeneron's information (a decision that differs by Defendant), and then brand multiple versions of the document bearing the appropriate Bates number and confidentiality designation for each Defendant. As a practical matter, that process typically takes days, not hours. Thus, Regeneron respectfully requests the following adjustments to Amgen's proposal:

- Paragraph 6 of Amgen's proposed order be changed to require that all redactions be provided to the party whose obligation it is to serve or file a redacted pleading within three (3) business days of any request;
- Paragraph 5 of Amgen's proposed order be changed to require Regeneron to serve non-public copies of sealed court orders seven (7) calendar days—rather than three (3) business days—after docketing. This change will permit Regeneron enough time to process any redacted copies of documents received from Defendants three business days after the Order's entry (pursuant to revised Paragraph 6).

## **II. Past Filings and Deposition Transcripts**

Amgen's proposed order applies only to docket entries dated after June 11, 2024, and therefore ignores all documents filed or served before that date. That omission means the public remains without access to the vast majority of docket entries in the ongoing injunctive proceedings, and leaves the parties—especially Regeneron—unclear as to what information may or may not safely be referenced in subsequent filings. This issue may arise in the ongoing injunction briefing or future motions for intervention, and will certainly arise during future proceedings at trial.

For a time, Amgen *also* sought access to past pleadings and supporting materials. Recently, however, Defendants provided redacted copies of certain select documents requested by Amgen. Amgen now has what it believes it needs, but the public and Regeneron do not. Defendants largely have refused to provide redacted copies of any additional briefs, declarations, or deposition transcripts, frustrating the public's right of access and Regeneron's ability to reference information appropriately in subsequent filings. Unfortunately, it appears an Order of this Court is necessary to remedy this problem, and to ensure that documents initially designated non-confidential remain so.

For example, Regeneron first requested confirmation that certain portions of the transcript of Dr. Boyle (an expert retained by Defendants Samsung Bioepis Co. Ltd. and Formycon AG), and Dr. Forrest (an expert retained by Defendant Formycon) more than two months ago, on April 6, 2024. *See* Ex. 2 at 5 (Formycon); Ex. 3 at 4-5 (Samsung). Regeneron has reiterated its request multiple times in the intervening eleven weeks, and has limited its request to confirmation that certain page and line numbers of the relevant transcripts do not contain Defendants' confidential information. Ex. 2 at 1-2 (Formycon); Ex. 3 at 1-3 (Samsung). There can be no meaningful dispute that the identified questions and answers are not confidential—Formycon and Samsung have not suggested otherwise, and instead assert that they have no obligation to respond to Regeneron's request.

Indeed, in the rare instances in which Defendants *do* comply with Regeneron's request to provide redacted versions of documents, they have not always honored their own redactions. For example, Formycon filed a declaration of its expert Dr. Boyle on March 21, 2024. Regeneron thereafter requested that Formycon provide a copy of Dr. Boyle's declaration that redacted all of Formycon's confidential information, and Formycon did so on March 27, 2024. Ex. 4 at 1. Regeneron sought to use that "public" version of Dr. Boyle's declaration during its deposition of Dr. Boyle in the Samsung case, so that it could simplify its deposition and appropriately adduce non-confidential testimony common to both cases. However, when Regeneron marked the exhibit, Samsung's counsel stopped the deposition and enlisted the assistance of Formycon's counsel, who (blaming a paralegal) promptly decided that the redacted copy of Dr. Boyle's declaration was confidential after all. Months later, Formycon still has not provided a replacement (and *permanently* non-confidential) version of Dr. Boyle's declaration. Ex. 5 at 1-3.

The stipulated protective orders in each case prohibit Regeneron from using one Defendant's confidential information in the case against a second Defendant. The protective orders do not, however, restrict the flow or use of *non*-confidential information. Defendants' papers, declarations, and deposition transcripts reflect numerous non-confidential statements about common issues across the MDL—for example, claim construction—that will continue to be litigated in these and other cases. The public is entitled to access those statements, and Regeneron should be entitled to reference them freely.

Now that all parties are united under a single MDL caption and therefore have the opportunity to be heard in these proceedings, Regeneron respectfully requests that the Court order each Defendant to serve Regeneron with redacted copies of all sealed filings and deposition transcripts applicable to their respective cases, removing all Defendant confidential information. Regeneron will then produce those redacted copies to all parties, consistent with various outstanding discovery requests. After adding redactions to protect its own confidential information, Regeneron will facilitate the public docketing of any document previously filed under seal. Recognizing that Defendants Mylan and Biocon are already engaged with Regeneron in facilitating public access to documents filed *before* injunctive proceedings began in that case, Regeneron proposes that process continue.

### III. Conclusion

Regeneron respectfully requests that the Court enter its proposed order, submitted herewith.

Alterations to the proposed order requested by Amgen are shown in redline in Exhibit 1.

Date: June 26, 2024

Respectfully Submitted:

Of counsel:

David I. Berl (admitted *PHV*)  
Ellen E. Oberwetter (admitted *PHV*)  
Thomas S. Fletcher (admitted *PHV*)  
Andrew V. Trask (admitted *PHV*)  
Teagan J. Gregory (admitted *PHV*)  
Shaun P. Mahaffy (admitted *PHV*)  
Kathryn S. Kayali (admitted *PHV*)  
Arthur J. Argall III (admitted *PHV*)  
Adam Pan (admitted *PHV*)  
Haylee N. Bernal Anderson (admitted *PHV*)  
Renee M. Griffin (admitted *PHV*)  
Jennalee Beazley (admitted *PHV*)  
WILLIAMS & CONNOLLY LLP  
680 Maine Avenue, SW  
Washington, DC 20024  
(202) 434-5000  
dberl@wc.com  
eoberwetter@wc.com

/s/ Steven R. Ruby

Steven R. Ruby (WVSB No. 10752)  
David R. Pogue (WVSB No. 10806)  
Raymond S. Franks II (WVSB No. 6523)  
CAREY DOUGLAS KESSLER & RUBY,  
PLLC  
707 Virginia Street East  
901 Chase Tower (25301)  
P.O. Box 913  
Charleston, West Virginia 25323  
(304) 345-1234  
sruby@cdkrlaw.com  
drpogue@cdkrlaw.com  
rfranks@cdkrlaw.com

*Attorneys for Plaintiff Regeneron  
Pharmaceuticals, Inc.*

# 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.