

**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-03103-TSK
Hon. Thomas S. Kleeh

**THIS DOCUMENT RELATES TO:
ALL CASES**

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT AMGEN INC.'S
EXPEDITED MOTION REQUIRING FILING AND SERVING OF
REDACTED VERSIONS OF SEALED FILINGS**

Defendant Amgen Inc. (“Amgen”) submits this Memorandum in Support of its Expedited Motion Requiring Filing and Serving of Redacted Versions of Sealed Filings. The requested relief is set forth in the attached Proposed Order, which specifies a procedure for ensuring that all parties to this Multidistrict Litigation (“MDL”) will have timely, equitable, and orderly access to judicial materials, particularly on common issues. The other MDL Defendants have agreed to the Proposed Order and indicated that they do not oppose Amgen’s motion.¹ This request is now urgent due to the Court’s issuance yesterday of a sealed injunction decision in one of these MDL cases (and the expected issuance of more in other MDL cases) that could affect time sensitive proceedings.

Regeneron Pharmaceuticals, Inc. (“Regeneron”) has not consented to the Proposed Order. However, Regeneron told this Court that allowing parties to consider this Court’s decisions across the MDL would “serve interest of efficiency and consistency by ensuring that Regeneron’s *Amgen*

¹ These other MDL defendants are Mylan Pharmaceuticals Inc. (“Mylan”), Biocon Biologics Inc. (“Biocon”), Celltrion, Inc. (“Celltrion”), Samsung Bioepis Co., Ltd. (“SB”), Formycon AG (“Formycon”), and Amgen Inc. (“Amgen”) (collectively, “MDL Defendants”).

motion comports with the Court’s earlier decisions,” otherwise “the parties would need to burden the Court with supplemental briefing to account for the Court’s decisions in these other cases, which may narrow or otherwise inform issues in the Amgen case.” Regeneron’s May 10, 2024 Submission at Ex. 4, pp. 2-3 (submitted via email).

With Amgen’s opposition to Regeneron’s preliminary injunction motion due in less than a month (on July 3), and depositions scheduled as early as next week, an expedited briefing schedule is needed such that any opposition to this motion should be due within three (3) business days.

I. Request to Enter the Attached Proposed Order

In its order creating this MDL proceeding and transferring Amgen’s case, the Judicial Panel on Multidistrict Litigation (“JPML”) found that these actions “involve common questions of fact” such that “centralization in the Northern District of West Virginia will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation.” 1:24-md-3403, ECF No. 1 at 1. The JPML further ordered centralization to “avoid the risk of duplicative discovery and prevent inconsistent rulings as to claim construction, patent validity, and other issues.” *Id.* at 2.

On June 11, 2024, this Court issued a sealed decision resolving Regeneron’s motion for a permanent injunction against Mylan and Biocon. 1:24-md-3403, ECF No. 162. Only Regeneron and Biocon can see the contents of this decision. Other decisions in other MDL cases are expected to issue shortly that could affect the proceedings against Amgen.

In view of the importance and time sensitivity around providing access to judicial materials within this MDL, the MDL Defendants made efforts to reach agreement on a procedure to facilitate timely, equitable, and orderly access to judicial materials. That consensus procedure is set forth in the attached Proposed Order. Amgen reached out to the MDL Defendants who each indicated that they do not oppose the Proposed Order. Amgen reached out to the MDL Defendants who each

indicated that they do not oppose this motion. The only party to the MDL who has not consented is Regeneron.

A. Access to Parties in the MDL

It is important for all parties in this MDL to receive access to versions of judicial materials that appropriately redact and keep under seal confidential information. Such access is important to further the JPML's objective of minimizing the risk of "inconsistent rulings." ECF No. 1 at 2.

On June 7, 2024, Regeneron filed its motion for a preliminary injunction against Amgen. Amgen's opposition is due in less than one month (on July 3). In the next three weeks, Amgen will be deposing Regeneron's witnesses Bernhardt Trout, Sean Sheridan, and Kevin Clark, whose prior testimony is likely to have been considered, if not expressly addressed, by this Court. There could be decisions by this Court related to claim construction and patent validity that may affect matters in the Amgen proceeding. It is therefore important for Amgen to consider this Court's decisions. As Regeneron stated in its May 10 Position Statement, allowing parties to consider such decisions: "[W]ill serve interest of efficiency and consistency by ensuring that Regeneron's *Amgen* motion comports with the Court's earlier decisions. Otherwise, it is likely the parties would need to burden the Court with supplemental briefing to account for the Court's decisions in these other cases, which may narrow or otherwise inform issues in the Amgen case." Regeneron's May 10, 2024 Submission at Ex. 4, pp. 2-3 (submitted via email).

As this Court recognized at the case management conference conducted on May 17, access to sealed materials has been a "frustration" to date. 1:24-md-3403, ECF No. 111 at 19:23-25. Ordering a formal procedure will minimize such frustrations by creating a process for ensuring timely access to redacted filings to all parties in the MDL. The MDL Defendants have worked together to settle on a proposed order to address this issue. All parties except Regeneron have agreed to the attached Proposed Order as an appropriate procedure for ensuring timely access to

future sealed filings.

Specifically, the parties (including Regeneron) have exchanged correspondence since May 21, 2024 (shortly after the case management conference) regarding access to judicial records and all parties to the MDL participated in several meet and confers in an effort to reach consensus on these issues. Exs. 1 and 2 (email correspondence and proposed stipulation); *see also* Exs. 3 and 4 (email correspondence confirming meet and confers on May 28 and June 10). After remaining silent for weeks, and only after all of the other MDL parties had already agreed to the Proposed Order on June 4, 2024, did Regeneron raise its concerns during a meet and confer on June 10, 2024. Ex. 5, at 1. Last night, at 10:09 pm ET, Regeneron proposed a series of revisions to the Proposed Order, several of which incorporate edits that certain parties had already rejected and resolved not to include in the attached Proposed Order in the interest of compromise. Exs. 5 and 6, at 2-4. Due to the time sensitive nature of preliminary injunction proceedings, and the need to make redacted versions of this Court's orders available to all parties in the MDL, Amgen is forced to bring an urgent motion to seek resolution on these access issues.

On the June 10, 2024 meet and confer, Regeneron voiced a concern that the Proposed Order does not allow Regeneron to share one defendant's confidential information with other defendants. That should not prevent entry of the attached Proposed Order. This Court has acknowledged that the defendants in this MDL are competitors and have a proprietary interest in not allowing their respective confidential information to be shared with other defendants by Regeneron. Specifically, during a case management conference related to the preliminary injunction proceedings, the Court ruled that the defendants' confidential information would be "siloed." No. 1:23-cv-89, ECF 107 at 6-7 (N.D.W. Va. Feb. 15, 2024) ("I think the same concerns would overflow, in all candor, to the anticipated preliminary injunction ... supporting briefs should be filed with respect to each

separate civil action and defendant.... I think each matter should be siloed, again, out of abundance of caution, to preserve any proprietary interests defendants may have in certain of these biosimilar products.”). The Court’s siloing approach is consistent with the protective orders that Regeneron already agreed to in each case. The Proposed Order preserves the Court’s case management order while enabling access to non-confidential versions for all parties.

Because Regeneron is the only party to this MDL *that already has access to all the sealed filings*, Regeneron may feel no individual need for the Proposed Order. However, basic notions of fair play dictate that all the MDL Defendants should have equal access to decisions in this MDL. A decision in one case may affect a decision in another case, and timely access so that the MDL Defendants can consider redacted versions of those decisions is important to reduce the risk of inconsistency.

There is good cause and an immediate need to enter the attached Proposed Order so that redacted versions of Court decisions are made accessible to all MDL parties. This formal procedure will facilitate timely, equitable, and ordered access to litigation materials in this MDL. Providing a formal procedure will also minimize motions practice by creating a default for timely access.²

B. Public Access to Judicial Proceedings

This Proposed Order also addresses the need for public versions of Sealed Court Orders to be filed on the public docket in view of the public’s right of access to judicial proceedings. *Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 597 (1978); *see also In re Application of U.S. for an Order Pursuant to 18 U.S.C. Section 2703(d)*, 707 F.3d 283, 290 (4th Cir. 2013). This is consistent with Local Rule of Civil Procedure 26.05(b), which states: “The rule requiring public inspection

² While much of the briefing is under seal, Formycon also filed a motion to compel documents produced in the *Mylan* litigation. 1:23-cv-97, ECF Nos. 131, 179, 180.

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