

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

IN RE: AFLIBERCEPT PATENT
LITIGATION

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

This Document Relates to All Cases

REGENERON PHARMACEUTICALS, INC.'S MAY 10, 2024 SUBMISSION

Pursuant to the Court's Order dated April 26, 2024, Plaintiff Regeneron Pharmaceuticals Inc. ("Regeneron") hereby submits its: (1) Position Statement; (2) suggestions as to the case management orders and additional agenda items for the May 17, 2024 Conference; and (3) recommendation for Regeneron's liaison counsel. Dkt. No. 24, ¶¶ 3-4, 18. Critically, and as explained further below, Regeneron respectfully requests that the Court include the following two items for discussion at the May 17, 2024 Conference: (1) the MDL Defendants' planned timing—absent Court order—for launching their respective biosimilar products in view of EYLEA's May 18, 2024 expiry of regulatory exclusivity; and (2) Regeneron's pending injunction motions and forthcoming motions for temporary restraining order, as discussed in Regeneron's Motion for Guidance regarding Temporary Restraining Orders in view of the May 18, 2024 Expiration of Regulatory Exclusivity for EYLEA (No. 24-md-3103, Dkt. No. 36).

I. Position Statement

Pursuant to paragraph 4 of the Court's Order, Regeneron provides its preliminary understanding of the facts involved in the litigation and the critical factual and legal issues, as well as a list of all related cases pending in state or federal court (together with their current status, including any discovery taken to date). Regeneron also attaches a list of motions pending in the member cases. Ex. 1.

Regeneron submits this Position Statement with the understanding that the statements herein will not be binding, will not waive any claims or defenses, and may not be offered in evidence against Regeneron in later proceedings. No. 24-md-3103, Dkt. No. 24, ¶ 3.

A. Preliminary Understanding of the Facts Involved in the Litigation and the Critical Factual and Legal Issues

The Defendants in the MDL member cases 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”). Mylan, Celltrion, SB, Formycon, and Amgen each filed a Biologics License Application (“BLA”) with FDA seeking approval to market their respective proposed biosimilar versions of Regeneron’s market-leading drug EYLEA, indicating their intents to market and distribute their respective biosimilars throughout the United States, including in West Virginia. Mylan later transferred ownership of its BLA to Biocon, who was added as Mylan’s co-defendant. Each MDL Defendant initiated and engaged in the BPCIA pre-litigation “patent dance” exchanges under 42 U.S.C. § 262(*l*). Regeneron filed complaints pursuant to 42 U.S.C. § 262(*l*), 35 U.S.C. § 271 and/or 28 U.S.C. § 2201, alleging that each of the respective biosimilar products will infringe certain of Regeneron’s patents, and seeking injunctive relief to enjoin each MDL Defendant, and all persons acting at an MDL Defendant’s direction, from launching its proposed biosimilar product. Each asserted claim of Regeneron’s asserted patents is not invalid; each claim asserted against a respective MDL Defendant will be infringed by that MDL Defendant’s corresponding biosimilar product absent an injunction. Regeneron will be irreparably injured if Regeneron’s pending and forthcoming motions for injunction are not granted, the balance of hardships favors Regeneron, and the public interest will be furthered by the requested injunctions.

Regeneron’s preliminary understanding of the critical factual and legal issues common to

two or more of the member cases includes: (1) whether the proposed biosimilar products infringe the patents (including U.S. Pat. No. 11,084,865 (“the Product Patent”)) that are commonly asserted across one or more of the member cases, including claim construction of any disputed terms from those patents; (2) whether those patents are not invalid; (3) whether injunctive relief is appropriate; and (4) whether Regeneron has established a reasonable probability of ultimate success on the question of personal jurisdiction with respect to direct-file defendants SB, Celltrion, and Formycon.

Further details regarding the facts and critical issues in each member case are provided below.

B. List of Related Cases Pending in State or Federal Court with Respective Statuses

1. Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. and Biocon Biologics Inc., No. 1:22-cv-61-TSK (N.D. W.Va.)

Mylan filed BLA No. 761274, seeking approval from FDA to commercialize M710, its biosimilar version of EYLEA, and initiated the patent dance. On August 2, 2022, after the parties had completed the patent dance, Regeneron filed a complaint pursuant to 42 U.S.C. § 262(l)(6) seeking a judgment of patent infringement against Mylan under 35 U.S.C. § 271(e). Mylan and Regeneron subsequently stipulated, and the Court ordered, joining Biocon as a Defendant. The Court held a bench trial on a subset of the asserted patents from June 12-23, 2023, and on December 27, 2023, the Court issued a 313-page opinion finding claims 4, 7, 9, 11, and 14-17 of the Product Patent infringed and not invalid. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2024 WL 382495 (N.D.W. Va. Jan. 31, 2024). On February 22, 2024, Regeneron filed a motion for permanent injunction to enjoin Mylan and Biocon, and all persons acting at their direction, from launching M710. The parties agreed to a schedule and proceeded to take limited discovery related

to Regeneron's motion. The motion is fully briefed and the parties await an oral argument date.

Because the Court has already concluded that the Product Patent is infringed and not invalid, the only critical factual and legal issues with respect to this phase of the case are whether Regeneron will be irreparably injured if a permanent injunction is not granted, whether the balance of hardships favors Regeneron, and whether the public interest will be furthered by an injunction.

Pursuant to the Court's Scheduling Order and ensuing orders (No. 22-cv-61, Dkt. Nos. 87, 698), following the conclusion of the first phase of litigation (in which Regeneron selected a subset of asserted patents for rapid adjudication), the parties will litigate the other asserted patents. Pre-trial proceedings for that phase of the litigation should be part of the coordinated MDL proceedings, pursuant to the transfer Order of the Judicial Panel on Multidistrict Litigation ("JPML") (No. 24-md-3103, Dkt. No. 1), as they will involve many of the same patents asserted against one or more of the other MDL Defendants. Regeneron understands that Defendants Mylan and Biocon believe that their case should be prioritized and heard more quickly than cases against the other MDL Defendants. Regeneron respectfully submits that this argument has already been heard and rejected both by this Court (No. 22-cv-61-TSK, Dkt. No. 691 (Mylan's motion for an expedited schedule on remaining patents); *id.* at Dkt. No. 698 (denying Mylan's motion)) and by the JPML (No. 24-md-3103, Dkt. No. 1; *see also* MDL No. 3103, Dkt. No. 26 (Mylan's and Biocon's response in opposition to transfer). As Regeneron reiterated in its responses to Mylan's earlier arguments (No. 22-cv-61-TSK, Dkt. No. 697 (Regeneron's opposition to Mylan's motion for expedited schedule); MDL No. 3103, Dkt. No. 29 at 7-8 (addressing Mylan's argument before the JPML))), there is no reason to expedite further proceedings against Mylan or Biocon given their infringement of the Product Patent, which does not expire until June 2027. Furthermore, the goals of efficiency and consistency will best be served by coordinated proceedings on the many patents

applicable to more than one Defendant, as the JPML determined. No. 24-md-3103, Dkt. No. 1 at 1-2.

2. *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc., No. 1:23-cv-00089-TSK (N.D. W.Va.)*

Celltrion filed BLA No. 761377, seeking approval to commercialize CT-P42, its biosimilar version of EYLEA, and initiated the patent dance. Dkt. No. 1, ¶23. On November 8, 2023, Regeneron filed a complaint pursuant to 42 U.S.C. § 262(l)(9)(A), seeking declaratory judgment of patent infringement against Celltrion under 35 U.S.C. §§ 271(a)-(c) and (g), and a judgment of patent infringement against Celltrion under 35 U.S.C. § 271(e).¹

On January 9, 2024, the Court entered a schedule for preliminary injunction proceedings. Regeneron filed a motion for preliminary injunction against Celltrion based on the Product Patent and U.S. Patent No. 11,793,926 (“Sterile Barrier Patent”), Celltrion filed its opposition, and Regeneron filed its reply. Consistent with the Court’s order, the parties engaged in limited discovery related to Regeneron’s motion, including exchanging document requests, producing documents, and taking depositions of each party’s declarants. The motion is fully briefed, and the parties await an oral argument date.

The critical factual and legal issues at this stage of the case are whether Regeneron is likely to succeed on the merits of the Product Patent and the Sterile Barrier Patent, whether Regeneron will be irreparably injured if an injunction is not granted, whether the balance of hardships favors Regeneron, whether the public interest will be furthered by an injunction, and whether Regeneron has established a reasonable probability of ultimate success upon the question of jurisdiction. As

¹ The parties have since completed the patent dance, and a second complaint pursuant to 42 U.S.C. § 262(l)(6) seeking a judgment of patent infringement against Celltrion under 35 U.S.C. § 271(e) is forthcoming.

the case progresses, the critical factual and legal issues will be whether CT-P42 infringes the Product Patent, the Sterile Barrier Patent, and the remaining patents asserted in Regeneron's complaint, and whether those patents are not invalid.

3. *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-00094-TSK (N.D. W.Va.); *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-00106-TSK (N.D. W.Va.)

SB filed BLA No. 761350 with FDA, seeking approval to commercialize SB15, a biosimilar version of EYLEA, and initiated the patent dance. Regeneron filed a complaint pursuant to 42 U.S.C. § 262(l)(9)(A), seeking declaratory judgment of patent infringement against SB under 35 U.S.C. §§ 271(a)-(c) and (g), and a judgment of patent infringement against SB under 35 U.S.C. § 271(e). After the parties completed the patent dance, Regeneron filed a second complaint pursuant to 42 U.S.C. § 262(l)(6) seeking a judgment of patent infringement against SB under 35 U.S.C. § 271(e).

On January 9, 2024, the Court entered a schedule for preliminary injunction proceedings. Regeneron filed a motion for preliminary injunction against SB based on the Product Patent and U.S. Patent Nos. 11,104,715, 11,472,861, and 11,535,663 ("Manufacturing Patents"), SB filed its opposition, and Regeneron filed its reply. Consistent with the Court's order, the parties engaged in limited discovery related to Regeneron's motion, including exchanging document requests, producing documents, and taking depositions of each party's declarants.² The motion is fully briefed and the parties await an oral argument date.

² In connection with Regeneron's motion for preliminary injunction on the Manufacturing Patents, Regeneron moved to compel third party SAFC BioSciences, Inc. in the U.S. District Court for the District of Kansas. *Regeneron Pharms., Inc. v. SAFC BioSciences, Inc.*, No. 2:24-mc-201 (D. Kan.). The motion was transferred to this Court on March 12, 2024, and is currently pending before the Court. *Regeneron Pharms., Inc. v. SAFC BioSciences, Inc.*, No. 24-cv-00029, Dkt. No. 22 (N.D.W. Va Mar. 12, 2024).

The critical factual and legal issues at this stage of the case are whether Regeneron is likely to succeed on the merits of the Product Patent and the Manufacturing Patents, whether to grant Regeneron's motion to compel documents from SAFC BioSciences, Inc., whether Regeneron will be irreparably injured if an injunction is not granted, whether the balance of hardships favors Regeneron, whether the public interest will be furthered by an injunction, and whether Regeneron has established a reasonable probability of ultimate success upon the question of jurisdiction. As the case progresses, the critical factual and legal issues will be whether SB15 infringes the Product Patent, the Manufacturing Patents, and the remaining patents asserted in Regeneron's complaint, and whether those patents are not invalid.

4. *Regeneron Pharmaceuticals, Inc. v. Formycon AG, No. 1:23-cv-00097-TSK (N.D. W.Va.)*

Formycon filed BLA No. 761378 with FDA, seeking approval to commercialize FYB203, its biosimilar version of EYLEA, and initiated the patent dance. Dkt. No. 1, ¶19. On November 29, 2023, Regeneron filed a complaint pursuant to 42 U.S.C. § 262(l)(9)(A), seeking declaratory judgment of patent infringement against Formycon under 35 U.S.C. §§ 271(a)-(c) and (g), and a judgment of patent infringement against Formycon under 35 U.S.C. § 271(e).

On January 9, 2024, the Court entered a schedule for preliminary injunction proceedings. Regeneron filed a motion for preliminary injunction against Formycon based on the Product Patent and the Manufacturing Patents, Formycon filed its opposition, and Regeneron filed its reply. Consistent with the Court's order, the parties engaged in limited discovery related to Regeneron's motion, including exchanging document requests, producing documents, and taking depositions of each party's declarants.³ The motion is fully briefed and the parties await an oral argument

³ In connection with Regeneron's motion for preliminary injunction on the Manufacturing Patents,

date.

The critical factual and legal issues at this stage of the case are whether Regeneron is likely to succeed on the merits of the Product Patent and the Manufacturing Patents, whether to grant Regeneron's motion to compel documents from SAFC BioSciences, Inc., whether Regeneron will be irreparably injured if an injunction is not granted, whether the balance of hardships favors Regeneron, whether the public interest will be furthered by an injunction, and whether Regeneron has established a reasonable probability of ultimate success upon the question of jurisdiction. As the case progresses, the critical factual and legal issues will be whether FYB203 infringes the Product Patent, the Manufacturing Patents, and the remaining patents asserted in Regeneron's complaint, and whether those patents are not invalid.

5. *Regeneron Pharmaceuticals, Inc. v. Amgen Inc., No. 1:24-cv-00039-TSK (N.D. W.Va.)*

Amgen filed BLA No. 761298 with FDA, seeking approval to commercialize ABP938, its biosimilar version of EYLEA, and initiated the patent dance. Dkt. No. 1, ¶19. On January 10, 2024, after the parties completed the patent dance, Regeneron filed a complaint in the U.S. District Court for the Central District of California pursuant to 42 U.S.C. § 262(l)(6) seeking a judgment of patent infringement against Amgen under 35 U.S.C. § 271(e). Regeneron proposed proceeding in the U.S. District Court for the Central District of California on the same preliminary injunction schedule as in the U.S. District Court for the Northern District of West Virginia, however, Amgen refused, and Regeneron thus filed a motion before the U.S. Judicial Panel on Multidistrict

Regeneron moved to compel third party SAFC BioSciences, Inc. in the U.S. District Court for the District of Kansas. *Regeneron Pharms., Inc. v. SAFC BioSciences, Inc.*, No. 2:24-mc-201 (D. Kan.). The motion was transferred to this Court on March 12, 2024, and is currently pending before the Court. *Regeneron Pharms., Inc. v. SAFC BioSciences, Inc.*, No. 24-cv-00029, Dkt. No. 22 (N.D.W. Va Mar. 12, 2024).

Litigation to transfer the action. On April 11, 2024, the U.S. Judicial Panel on Multidistrict Litigation transferred the case to this Court for coordinated or consolidated pretrial proceedings. MDL No. 3103, Dkt. No. 1.

The parties began negotiating a schedule for preliminary injunction proceedings and engaged in limited discovery related to Regeneron's forthcoming motion for preliminary injunction, including exchanging initial document requests and producing documents related to the subset of patents Regeneron identified for the preliminary injunction proceedings—The Product Patent, the Sterile Barrier Patents, the Manufacturing Patents, and U.S. Patent Nos. 11,160,918 and 11,548,932. The parties dispute the appropriate schedule and scope of preliminary injunction proceedings; Regeneron therefore provides its proposed schedule herein (Ex. 4).⁴

The critical factual and legal issues at this stage of the case are whether Regeneron is likely to succeed on the merits of patents identified for preliminary injunction proceedings, whether Regeneron will be irreparably injured if an injunction is not granted, whether the balance of hardships favors Regeneron, and whether the public interest will be furthered by an injunction. As the case progresses, the critical factual and legal issues will be whether ABP938 infringes those patents and the remaining patents asserted in Regeneron's complaint, and whether those patents are not invalid.

II. Suggestion for Case Management Orders and Additional Agenda Items for the May 17, 2024 Conference

Pursuant to paragraph 3 of the Court's Order, Regeneron provides suggestions as to the case management orders and additional agenda items for the May 17, 2024 Conference. Regeneron further confirms that the parties met and conferred on May 7, 2024 regarding a

⁴ This document contains information Amgen considers confidential and therefore has been served only on Amgen's counsel.

proposed discovery plan. No consensus was reached; therefore, Regeneron provides its position regarding a discovery plan below.

C. Case Management Orders

Regeneron proposes phasing discovery in light of Regeneron's pending and forthcoming motions for injunctive relief. MCL 4th § 11.421. The first phase would relate to Regeneron's motions for injunctive relief, which as explained above is already underway and, other than Amgen (*supra* I.B.5; Ex. 4), is near complete. The second phase would relate to the remaining issues in the litigation. It would be premature at this time to propose a discovery plan as to the remaining issues before the Court resolves Regeneron's injunction motions. The MCL acknowledges that:

Counsel and the judge will rarely be able to determine conclusively early in the litigation what discovery will be necessary; some discovery of potential relevance at the outset may be rendered irrelevant as the litigation proceeds, and the need for other discovery may become known only through later developments. For effective discovery control, initial discovery should focus on matters—witnesses, documents, information—that appear pivotal. As the litigation proceeds, this initial discovery may render other discovery unnecessary or provide leads for further necessary discovery.

Id.

Regeneron proposed the above plan during a meet and confer with MDL Defendants. MDL Defendants did not agree to Regeneron's proposal, and instead insisted that Regeneron provide a proposed discovery plan first despite Regeneron's clear position that such a plan would be premature. Regeneron later offered to exchange schedules at a mutually agreed-upon time; the MDL Defendants refused to engage in a mutual exchange despite admitting that they had or were developing proposed schedules. Regeneron ultimately provided its schedule to MDL Defendants in advance of their submissions, but not all MDL Defendants (Mylan and Biocon) extended Regeneron that same courtesy. For their part, Celltrion, SB, and Formycon provided a joint schedule after Regeneron provided its schedule, and Amgen provided a schedule thereafter.

Regeneron does not agree with defendants' proposed schedules, including because they require Regeneron to unilaterally reduce the number of asserted patents before discovery or claim construction proceedings and without any commensurate narrowing of defenses by MDL Defendants. That is contrary both to precedent and basic fairness: "A court must exercise the authority to order a reduction in the number of asserted claims with care not to prejudice the patentee, particularly in light of the fact that each of the claims of a patent embodies a property right"; accordingly, "claim reduction should not be ordered 'too early in the discovery process' because doing so would deny the patentee 'the opportunity to determine whether particular claims might raise separate issues of infringement or invalidity in light of the defendants' accused products and proposed defenses.'" *Allergan, Inc. v. Teva Pharms. USA*, 2017 WL 373462, at *2 (E.D. Tex. Jan. 26, 2017) (quoting *In re Katz*, 639 F.3d 1303, 1309 (Fed. Cir. 2011)). Nonetheless, Regeneron remains willing to discuss the parties' respective proposals over the next week in advance of the Court's May 17 Conference. Accordingly, Regeneron reserves all rights to supplement, revise, or otherwise amend its proposed discovery plan schedule, in view of the parties' ongoing discussions and in response to the MDL Defendants' submissions.

As noted, Regeneron continues to believe that drafting a discovery plan for the subsequent phase of the litigation is premature at this time. To the extent the Court agrees with MDL Defendants, however, Regeneron alternatively proposes the below discovery plan as to the subsequent phase of litigation following resolution of Regeneron's motions for injunctive relief. *See also* Ex. 2.

Regeneron proposes that the parties coordinate discovery and minimize duplication of issues for the parties and the Court. To that end, Regeneron proposes the following, consistent with the Federal Rules, with some modifications given the specific nature of this case: (1) each

witness (fact or expert) may be deposed only in a single 7-hour deposition (for clarity, that time is shared amongst MDL Defendants); (2) any party's fact witness who is deposed shall be deposed only a single time; (3) Regeneron and MDL Defendants (collectively) may each take 15 depositions of fact witnesses, including third parties (five more than the 10 allotted in the Federal Rules); (4) Regeneron shall be entitled to serve no more than 20 interrogatories commonly on all MDL Defendants (which each MDL Defendant may choose to answer with one or more other MDL Defendants or individually), and no more than five interrogatories on each Defendant Group individually⁵; (5) MDL Defendants shall collectively be entitled to serve no more than 20 common interrogatories on Regeneron, and each Defendant Group individually shall be entitled to serve no more than five additional interrogatories on Regeneron.

In the event the Court seeks to enter a schedule for the subsequent phase of litigation at this juncture, Regeneron proposes a schedule that minimizes the duplication of issues for the parties and the Court and positions the subsequent phase of litigation for trial in advance of the expiration of the Product Patent in June 2027. *See* No. 22-cv-61, Dkt. No. 698 (“The ‘865 patent does not expire until June 2027. As such, there is no urgent need to schedule a trial in October 2024 on the remaining patents.”). Accordingly, Regeneron proposes that the parties jointly submit a Rule 26(f) statement as to this phase on October 16, 2024 or 90 days from the Court’s Preliminary Injunction Order in the Formycon, Celltrion, and SB cases, whichever is earlier, and requests that the Court enter Regeneron’s Proposed Order Regarding Schedule and Discovery Plan set forth in Exhibit 2, which positions the subsequent phase for trial in July 2026. Regeneron’s proposed schedule permits the subsequent stage of litigation to proceed in parallel for all parties, thereby enhancing

⁵ The Defendant Groups are hereby defined as: (1) Mylan and Biocon; (2) Celltrion; (3) SB; (4) Formycon; (5) Amgen.

efficiency in these MDL proceedings.

D. Additional Agenda Items

The Court's Order identifies the following tentative agenda items for the May 17, 2024 Conference: discovery plan (MCL § 11.421), amendment of pleadings, and items listed in MCL §§ 22.6, 22.61, 22.62, and 22.63, to the extent applicable. Regeneron does not believe that the items listed in MCL §§ 22.6, 22.61, 22.62, and 22.63 are applicable to this case except for items relating to a discovery plan.

Given the imminent expiry of EYLEA's regulatory exclusivity on May 18, 2024, Regeneron respectfully requests that the Court include the following two items for discussion at the May 17, 2024 Conference: (1) the MDL Defendants' planned timing—absent Court order—for launching their respective biosimilar products in view of EYLEA's May 18, 2024 expiry of regulatory exclusivity; and (2) Regeneron's pending injunction motions and forthcoming motions for temporary restraining order, as discussed in Regeneron's Motion for Guidance regarding Temporary Restraining Orders in view of the May 18, 2024 Expiration of Regulatory Exclusivity for EYLEA (No. 24-md-3103, Dkt. No. 36).

III. One Recommendation for Regeneron's Liaison Counsel

Pursuant to paragraph 18 of the Court's Order, Regeneron recommends David I. Berl⁶ for the position of Regeneron's liaison counsel. Mr. Berl is lead counsel for Regeneron in the above-captioned case and associated member cases. He is a partner at Williams & Connolly LLP where his practice focuses on patent litigation in the biotechnology and pharmaceutical fields. Mr. Berl

⁶ Regeneron conferred with MDL Defendants regarding Regeneron's recommendation for its liaison counsel. MDL Defendants raised no objections to Mr. Berl at that time. MDL Defendants also did not propose any recommendations for their liaison counsel, but requested an increase from three liaison counsel to five liaison counsel. Regeneron does not oppose such a request.

obtained his J.D. from Stanford Law School in 2000, where he graduated Order of the Coif, and obtained his bachelor of science from the Massachusetts Institute of Technology in 1997. From 2001-2002, Mr. Berl clerked for the Honorable Alvin A. Schall for the U.S. Court of Appeals for the Federal Circuit.

Mr. Berl has extensive relevant experience with cases in similar areas as this one, including:

- Lead Counsel for Pfizer in MDL proceedings relating to applications to market generic versions of Pfizer's palbociclib (Ibrance) for the treatment of breast cancer. The MDL proceedings involved cases against thirteen generic manufacturers. The cases proceeded through discovery and were resolved by settlement before trial.
- Lead Counsel for Teva's Branded Division in a Hatch-Waxman trial in the United States District Court for the District of Delaware and the Federal Circuit, relating to multiple generic manufacturers' applications to market a generic version of its Bendeka product. After a seven-day bench trial, the court upheld the validity of all claims in all five patents. The Federal Circuit affirmed.
- Lead counsel for AstraZeneca in Hatch-Waxman litigation in the United States District Court for the Northern District of West Virginia and the Federal Circuit, relating to Mylan's application to market a generic version of AstraZeneca's Symbicort product. Following a bench trial, the Court ruled in favor of AstraZeneca as to all claims, rejecting Mylan's argument that the asserted claims were invalid. That ruling was affirmed on appeal.
- Lead counsel for Bayer Healthcare in a Hatch-Waxman trial against Watson in the United States District Court for the District of Delaware, relating to Watson's effort to market a generic version of Bayer Healthcare's erectile dysfunction drug vardenafil. The Court

ruled from the bench in Bayer Healthcare's favor, upholding the validity of Bayer Healthcare's patents directed to vardenafil.

- Lead counsel for Pfizer in a Hatch-Waxman trial against Actavis in the United States District Court for the District of Delaware. The case involved a challenge by Actavis to Pfizer's patent regarding its platform technology for avoiding the abuse of opioid drugs, embodied by its Embeda product.
- Lead counsel for Bayer in the Federal Circuit and district court in a patent suit filed by Biogen relating to treatments for multiple sclerosis. The district court dismissed the claims against Bayer on the basis of an interpretation of the America Invents Act, and the Federal Circuit affirmed the dismissal. Mr. Berl argued the case before the district court and the Federal Circuit.
- Co-Lead Counsel for MedImmune in its declaratory judgment action challenging the "Queen patents" assigned to PDL BioPharma, among the most widely licensed patent portfolios in the biotechnology industry. Mr. Berl argued, and the court ruled on summary judgment, that the asserted Queen patent was invalid as anticipated.
- Lead counsel for Genevant in litigation against Moderna relating to the COVID-19 vaccine in the District of Delaware and the Federal Circuit. Genevant prevailed in multiple appeals from Moderna's unsuccessful inter partes review challenge of two Genevant patents before the USPTO. The Federal Circuit dismissed Moderna's appeal with respect to one patent for lack of subject matter jurisdiction. The Federal Circuit affirmed the finding of no invalidity on the merits with respect to another patent Moderna challenged. The litigation in the District of Delaware asserting these patents and others is ongoing.
- Represented Wyeth in connection with district court, *inter partes* review, and appellate

proceedings regarding its antibiotic product Tygacil. In one of the first pharmaceutical *inter partes* review cases to proceed to trial and appeal, Mr. Berl argued successfully to the Patent Trial and Appeal Board that the claims of Wyeth's patent were valid. Mr. Berl also argued the case on appeal to the Court of Appeals for the Federal Circuit, which affirmed the Board's finding of validity.

Mr. Berl is licensed to practice before the Washington, D.C. Bar, the California State Bar, the U.S. Court of Appeals for the Federal Circuit, the U.S. District Court District of Maryland, and the U.S. Patent and Trademark Office. Mr. Berl's certificate of good standing and resume are attached here as Exhibit 3.

Date: May 10, 2024

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EXHIBIT 1

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

IN RE: AFLIBERCEPT PATENT LITIGATION

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

This Document Relates to All Cases

JOINT NOTICE OF PENDING MOTIONS

Pursuant to the Court's Order dated April 26, 2024, Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") and MDL Defendants Mylan Pharmaceuticals Inc. ("Mylan"), Biocon Biologics Inc. ("Biocon"), Samsung Bioepis Co., Ltd. ("SB"), Celltrion, Inc. ("Celltrion"), Formycon AG ("Formycon"), and Amgen Inc. ("Amgen") jointly submit this Notice of Pending Motions before the Court, with each motion identified by member case number and style as well as by the document number assigned to the motion. The parties understand that this Notice serves as re-notice of each pending motion for resolution and that the re-noticed motions will be considered pending as of the date of the filing of this Notice.

Regeneron further advises the Court that its Motion for Guidance Regarding Temporary Restraining Orders in View of May 18, 2024 Expiration of Regulatory Exclusivity for EYLEA, which Regeneron filed on May 3, 2024, is also pending before the Court in the above-captioned MDL and certain member cases. *See* No. 1:24-md-3103 Dkt. 36; No. 1:22-cv-00061-TSK, Dkt. 754; No. 1:23-cv-00089-TSK, Dkt. 168; No. 1:23-cv-00094-TSK, Dkt. 207; No. 1:23-cv-00106-TSK, Dkt. 189; No. 1:23-cv-00097-TSK, Dkt. 217; No. 1:24-cv-00039-TSK Dkt. 131.

I. *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc. and Biocon Biologics Inc.*, No. 1:22-cv-00061-TSK (N.D. W.Va.)

A. Regeneron's Pending Motions

Regeneron identifies and re-notices the following motions it has filed that are currently pending before the Court in the above-captioned case against Mylan and Biocon:

- Motion for Permanent Injunction (Case No. 1:22-cv-00061-TSK Dkt. 708)

B. Mylan's and Biocon's Pending Motions

None.

II. *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 1:23-cv-00089-TSK (N.D. W.Va.)

A. Regeneron's Pending Motions

Regeneron identifies and re-notices the following motions it has filed that are currently pending before the Court in the above-captioned case against Celltrion:

- Motion for Preliminary Injunction (Case No. 1:23-cv-00089-TSK Dkt. 108)

B. Celltrion's Pending Motions

Celltrion identifies and re-notices the following motions it has filed that are currently pending before the Court in the above-captioned case against Celltrion:

- Celltrion's Motion to Dismiss for Lack of Personal Jurisdiction or, Alternatively, Transfer Venue (Case No. 1:23-cv-00089-TSK Dkt. 68)
- Celltrion's Motion to Strike Portions of Regeneron's Reply Brief and the Entirety of the Graham Declaration, or, In the Alternative, for Leave to File a Sur-Reply (Case No. 1:23-cv-00089-TSK Dkt. 160-2)

III. *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-00094-TSK (N.D. W.Va.); *Regeneron Pharmaceuticals, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:23-cv-00106-TSK (N.D. W.Va.)

A. Regeneron's Pending Motions

Regeneron identifies and re-notices the following motions it has filed that are currently pending before the Court in the above-captioned cases against SB:

- Motion for Preliminary Injunction (Case No. 1:23-cv-00094-TSK Dkt. 118; Case No. 1:23-cv-00106-TSK Dkt. 99)
- Emergency Motion to Strike Samsung Bioepis's and Formycon's Motion to Strike (Case No. 1:23-cv-00094-TSK Dkt. 171; Case No. 1:23-cv-00106-TSK Dkt. 152)

B. SB's Pending Motions

SB identifies and re-notices the following motions it has filed that are currently pending before the Court in the above-captioned cases against SB:

- SB's Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(2) (Case No. 1:23-cv-94-TSK-JPM Dkt. 47; Case No. 1:23-cv-106-TSK-JPM Dkt. 14)
- SB's and Formycon's Motion for an Order Confirming That Third-Party Discovery Is Not Permitted (Case No. 1:23-cv-94-TSK-JPM Dkt. 129-2; Case No. 1:23-cv-106-TSK-JPM Dkt. 110-2)
- SB's and Formycon's Motion to Partially Strike the Opening Declaration of Dr. Ranjit Singh Atwal (Case No. 1:23-cv-94-TSK-JPM Dkt. 163-2; Case No. 1:23-cv-106-TSK-JPM Dkt. 143-2)
- SB's Emergency Motion to Strike (Case No. 1:23-cv-94-TSK-JPM Dkt. 195-2; Case No. 1:23-cv-106-TSK-JPM Dkt. 177-2);
- SB's Emergency Motion to Compel (Case No. 1:23-cv-94-TSK-JPM Dkt. 200-2; Case No. 1:23-cv-106-TSK-JPM Dkt. 182-2)

IV. *Regeneron Pharmaceuticals, Inc. v. Formycon AG*, No. 1:23-cv-00097-TSK (N.D. W.Va.)

A. Regeneron's Pending Motions

Regeneron identifies and re-notices the following motions it has filed that are currently pending before the Court in the above-captioned case against Formycon:

- Motion for Preliminary Injunction (Case No. 1:23-cv-00097-TSK Dkt. 101)
- Emergency Motion to Strike Samsung Bioepis's and Formycon's Motion to Strike (Case No. 1:23-cv-00097-TSK Dkt. 173)

B. Formycon's Pending Motions

Formycon identifies and re-notices the following motions it has filed that are currently pending before the Court in the above-captioned case against Formycon:

- Motion to Dismiss for Lack of Personal Jurisdiction or Alternatively to Transfer Venue (Case No. 1:23-cv-00097-TSK Dkts. 57-58)
- Motion for an Order Confirming That Third-Party Discovery Is Not Permitted (Case No. 1:23-cv-00097-TSK Dkt. 110)
- Motion to Partially Strike the Opening Declaration of Dr. Ranjit Singh Atwal (Case No. 1:23-cv-00097-TSK Dkt. 154)
- Objections to Magistrate Judge Mazzone's Sealed Order Denying Its Emergency Motion to Compel (Case No. 1:23-cv-00097-TSK Dkts. 179, 180)
- Emergency Motion to Strike (Case No. 1:23-cv-00097-TSK Dkt. 207 and MDL No. 1:24-MD-3103-TSK Dkt. 8)

V. *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, No. 1:24-cv-00039-TSK (N.D. W.Va.)

A. Regeneron's Pending Motions

Regeneron does not currently have any motions pending with the Court in the above-captioned case against Amgen.

B. Amgen's Pending Motions

Amgen identifies and re-notices the following motion it has filed that is currently pending before the Court in the above-captioned case:

- Defendant Amgen Inc.'s Motion to Compel (Case No. 1:24-cv-00039-TSK Dkt. 125)

In addition to the above motions, and in connection with Case Nos. 1:23-cv-00097, 1:23-cv-00094, 1:23-cv-00106, Regeneron identifies and re-notices the following motion it has filed that is currently pending before the Court in the non-member case captioned *Regeneron Pharmaceuticals, Inc. v. SAFC Biosciences, Inc.*, No. 1:24-mc-00029-TSK (N.D. W.Va.):

- Motion to Compel Compliance with Rule 45 Subpoenas (Case No. 1:24-mc-00029 Dkt. 20)

Date: May 10, 2024

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on the 10th day of May 2024, service of the foregoing *Joint Notice of Pending Motions* was made to counsel of record by CM/ECF filing.

/s/ Steven R. Ruby

Steven R. Ruby (WVSB No. 10752)

EXHIBIT 2

IN RE: AFLIBERCEPT PATENT
LITIGATION

This Document Relates to All Cases

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

[PROPOSED] ORDER REGARDING SCHEDULE AND DISCOVERY

Plaintiff Regeneron Pharmaceuticals Inc. (“Regeneron”) has brought several actions for patent infringement against defendants seeking to market biosimilar versions of its EYLEA product. On April 11, 2024, the Judicial Panel on Multi-District Litigation (JPML) entered an order centralizing the litigations in this Court. Dkt. 1. The Defendants in the MDL member cases 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”). Consistent with the Federal Rules of Civil Procedure and the Order of the JPML to avoid “duplicative discovery,” Dkt. 1 at 2, the Court hereby sets forth the following schedule and limitations on discovery for the subsequent phase of litigation in this matter following the proceedings regarding Regeneron’s requests for injunctive relief.

The Court hereby sets forth the following schedule governing subsequent proceedings:

	DATE
Rule 26(f) Conference of Parties on subsequent phase of litigation	60 days after Court’s Order on Preliminary Injunction or 9/19/2024, whichever is earlier
Joint Submission of Rule 26(f) Report	30 days after Rule 26(f) Conference or 10/16/2024, whichever is earlier
<i>Markman</i> : exchange of proposed patent claim terms for construction. <i>Plaintiff and Defendants can propose 10 terms for construction (5 for Plaintiff, 5 for Defendants collectively)</i>	10/31/2024
<i>Markman</i> : exchange of preliminary constructions and intrinsic support	11/7/2024

<i>Markman</i> : File joint claim construction chart	11/14/2024
<i>Markman</i> : parties file joint opening claim construction briefs	12/12/2024
<i>Markman</i> : parties file joint responsive claim construction briefs	1/16/2025
<i>Markman</i> hearing	1/30/2025, or at Court's Convenience
Substantial completion of document production	8/14/2025
Parties serve final infringement and invalidity contentions	10/9/2025
Close of Fact Discovery	10/16/2025
Opening Expert Reports on Issues for Which the Party Bears the Burden of Proof	12/11/2025
Responsive/Rebuttal Expert Reports	2/5/2026
Reply Expert Reports	3/19/2026
Close of Expert Discovery	5/14/2026
Motions <i>in Limine</i> and <i>Daubert</i> Motions	6/11/2026
Responses to Motions <i>in Limine</i> and <i>Daubert</i> Motions	6/18/2026
Joint Stipulation of Facts	6/25/2026
Proposed Joint Pretrial Order, L.R. Civ. P. 16.04(b)[1]	6/25/2026
Final Pretrial and Settlement Conference	7/ /2026
Trial	7/ /2026

With respect to ***Depositions***, the Court orders as follows:

- Each witness (fact or expert) may be deposed only in a single 7-hour deposition (for clarity, that time is shared amongst the MDL Defendants);
- Any party's fact witness who is deposed shall be deposed only a single time;
- Regeneron and the MDL Defendants (collectively) may each take 15 depositions of fact witnesses, including third parties (five more than the 10 allotted in the Federal Rules);

With respect to ***Interrogatories***, the following application of Fed. R. Civ. P. 33(a)(1) shall apply in view of the pretrial consolidation and coordination of the above-captioned cases.

- Regeneron shall be entitled to serve no more than 20 interrogatories commonly on all MDL Defendants (which each MDL Defendant may choose to answer with one or more other MDL Defendants or individually), and no more than five interrogatories on each Defendant Group individually¹;
- MDL Defendants shall collectively be entitled to serve no more than 20 common interrogatories on Regeneron, and each Defendant Group individually shall be entitled to serve no more than five additional interrogatories on Regeneron.

It is so **ORDERED**.

Thomas S. Kleeh, Chief Judge
Northern District of West Virginia

¹ The Defendant Groups are hereby defined as: (1) Mylan and Biocon; (2) Celltrion; (3) SB; (4) Formycon; (5) Amgen.

EXHIBIT 3



*On behalf of JULIO A. CASTILLO, Clerk of the District of Columbia Court of Appeals,
the District of Columbia Bar does hereby certify that*

David I Berl

*was duly qualified and admitted on July 11, 2003 as an attorney and counselor entitled to
practice before this Court; and is, on the date indicated below, an Active member in good
standing of this Bar.*

*In Testimony Whereof,
I have hereunto subscribed my
name and affixed the seal of this
Court at the City of
Washington, D.C., on May 07, 2024.*

Julio A. Castillo
JULIO A. CASTILLO
Clerk of the Court

Issued By:

A handwritten signature in black ink, appearing to read "David Chu".

*David Chu - Director, Membership
District of Columbia Bar Membership*

***For questions or concerns, please contact the D.C. Bar Membership Office at 202-626-3475 or email
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- (Oct. 2002-Jan. 2009)

Litigation

- (October 2002-Present)

Law clerk

- Judge Alvin A. Schall (U.S. Court of Appeals for the Federal Circuit) (2001-2002)

Additional Information:

Member of the Bars of the District of Columbia Court of Appeals, U.S. District Court for the Northern District of California, U.S. District Court for Maryland, U.S. District Court for the Central District of California, U.S. District Court for the Eastern District of Wisconsin, U.S. Court of Appeals for the Federal Circuit, and U.S. Patent and Trademark Office