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Subject: RE: In re Aflibercept Patent Litigation - Case No. 24-md-3101 / 23-cv-89, 24-cv-53, 23-cv-89, 23-cv-97, 23-cv-106
Date: August 9, 2024 at 10:06 PM
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Dear Ms. Gibson:

I write as liaison counsel for Plaintiff Regeneron Pharmaceuticals, Inc. in Case No. 24-md-3101.

Regeneron likewise submitted a proposed schedule on May 10 of this year, with dates that also require adjustment. As of May 10, the timeline for any appeals of the Court's (then-forthcoming) decisions on Regeneron's motions for preliminary and permanent injunctions was uncertain. Since that time, the Federal Circuit has issued an order controlling the schedule of briefing and ensuring all appeals will be heard by the same panel at the first available opportunity when briefing is complete, a request Regeneron did not oppose. Accordingly, Defendants now control the timing of the appeals by the timing of their opening briefs. At Defendants' insistence, each of Formycon, Celltrion, Samsung Bioepis, and Mylan/Biocon will file (or have already filed) separate appellate briefs.

Because it is now clear that the appeals will be briefed and heard on an expedited timeline through the Fall, Regeneron respectfully submits the attached proposed schedule for the Court's consideration. There is no need to adopt a schedule leading to trial on the merits next year on numerous patents, when the results of these appeals are likely to materially affect the scope, content, and appropriate timing of future proceedings. As the Court previously observed with respect to Mylan/Biocon (ECF No. 698 in Member Case No. 22-cv-61), and is now true of Formycon, Samsung Bioepis, and Celltrion in view of the Court's preliminary injunction decisions, no launch can occur before the June 2027 expiry of the Product Patent.

I have copied counsel for Regeneron, Amgen, Samsung Bioepis, Formycon, Celltrion, Mylan, and Biocon on this email.

Respectfully,

David Berl

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Subject: In re Aflibercept Patent Litigation - Case No. 24-md-3101 / 23-cv-89, 24-cv-53, 23-cv-89, 23-cv-97, 23-cv-106

Dear Ms. Gibson,

I write as Liaison Counsel for Formycon on behalf of Formycon, Celltrion, and Samsung Bioepis ("the FCS Defendants") in the above-captioned *In re Aflibercept* litigation.

On May 10, pursuant to the Court's first pretrial order, the FCS Defendants, as well as Mylan, Amgen, and Regeneron, submitted their respective proposed schedules. Since then, the earliest dates for deadlines proposed in the FCS Defendants' proposed schedule have already passed. Therefore, to aid the Court as it considers an appropriate schedule for these matters, the FCS Defendants have updated the proposed dates in their earlier proposed schedule with the revised deadlines set to begin on August 20, 2024, after the preliminary injunction hearing concerning Amgen. That updated schedule is attached here.

Defendants appreciate the Court's consideration of the parties' proposed schedules and stand ready to do what is necessary to help move this matter forward without delay. Given that the Court has cleared the preliminary injunction matters pertaining to the FCS Defendants and is poised to do the same for Amgen, the proceedings are ripe for their next stages. Counsel on behalf of the FCS Defendants plan to be present at the hearing on August 13 and will be happy to discuss any issues the Court might find helpful in entering a scheduling order for these matters.

I have copied counsel for Regeneron, Amgen, Samsung Bioepis, Formycon, Celltrion, Mylan, and Biocon on this email.

Sincerely,

Louis Fogel

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2024.08.09 - Regeneron
Proposed Schedule (24-md-310...
142 KB



**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**

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:

EVENT	DATE
Rule 26(f) Conference of Parties on subsequent phase of litigation	30 days after a decision on all appeals arising from this Court’s decisions on Regeneron’s motions for preliminary and permanent injunctions
Joint Submission of Rule 26(f) Report	30 days after Rule 26(f) Conference

<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>	14 days after submission of Rule 26(f) Report
<i>Markman</i> : exchange of preliminary constructions and intrinsic support	Seven days after exchange of proposed patent claim terms for construction
<i>Markman</i> : File joint claim construction chart	Seven days after exchange of preliminary constructions and intrinsic support
<i>Markman</i> : parties file joint opening claim construction briefs	30 days after parties file joint claim construction chart
<i>Markman</i> : parties file joint responsive claim construction briefs	30 days after parties file opening claim construction briefs
<i>Markman</i> hearing	14 days after parties file joint responsive claim construction briefs, or at the 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.