

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-3103-TSK

THIS DOCUMENT RELATES TO:

Civil Action No. 1:23-cv-94-TSK

Civil Action No. 1:23-cv-106-TSK

DEFENDANT SAMSUNG BIOEPIS CO., LTD.’S
MOTION FOR ENTRY OF SCHEDULING ORDER PURSUANT TO RULE 16
OR, IN THE ALTERNATIVE, A STATUS CONFERENCE

Defendant Samsung Bioepis Co., Ltd. (“SB”) hereby moves for entry of a scheduling order or, in the alternative, a status conference.

Regeneron Pharmaceuticals, Inc. (“Regeneron”) filed its cases against SB over a year ago. ECF No. 1.¹ The FDA approved SB’s aflibercept biosimilar, SB15, in May 2024, over nine months ago. But because Regeneron requested and was granted a preliminary injunction, which the Federal Circuit recently affirmed, SB cannot sell SB15 in the United States. ECF Nos. 316-317; ECF No. 243. Preliminary relief is no substitute for a full trial on the merits (*Faulkner v. Jones*, 10 F.3d 226, 234 (4th Cir. 1993)), and SB remains confident that such a trial will absolve it of any alleged infringement. Fairness dictates moving to trial quickly and requiring Regeneron to justify the extraordinary remedy of injunctive relief on a full record, including live witness presentations and cross-examinations. Yet trial has not yet been scheduled, nor is there any scheduling order to progress the parties toward trial.

Every day that SB remains barred from the market based on a preliminary decision harms SB. That harm is not abstract. Since the preliminary injunction was entered, Biogen, who held the exclusive right to sell SB15 in the US, notified SB it is terminating its commercialization agreement with SB. Additionally, Amgen, which filed for and received FDA approval well *after* SB, has now launched its aflibercept biosimilar, thereby taking away SB’s first-mover advantage. Every day that SB is barred from selling SB15 is another day for Amgen to gain a foothold in the aflibercept biosimilar market.

The Court held a scheduling conference in May 2024, but did not thereafter issue a scheduling order, apparently in deference to the ongoing preliminary injunction proceedings. ECF

¹ Unless otherwise specified, all citations are made to the 1:23-cv-94 docket. These documents are also available on the 1:23-cv-106 docket.

225. SB, along with the other defendants in this MDL, requested a status conference from the Court in September 2024 to discuss a schedule, a request Regeneron did not oppose. ECF Nos. 278, 280. The Court has not yet responded to the September request.

SB notes that Rule 16 provides that a court “must issue the scheduling order as soon as practicable”; in particular, absent good cause, the court must issue the order “within the earlier of 90 days after any defendant has been served with the complaint or 60 days after any defendant has appeared.” Fed. R. Civ. P. 16; *see also* Manual for Complex Litigation, Fourth, § 10.11. Regeneron served SB with its complaints on October 16, 2024, over 90 days ago. ECF No. 284. And the Federal Circuit recently affirmed the preliminary injunction, underlining the need to move to a trial on the merits quickly.

Accordingly, SB requests entry of a scheduling order pursuant to Rule 16 or, in the alternative, a status conference with the Court to discuss scheduling. Attached hereto as Exhibit A is SB’s proposed schedule for the Court’s consideration. SB’s schedule seeks a quick trial on the merits in view of the ongoing harm from the preliminary injunction. ECF Nos. 316-317; ECF No. 243. In order to accomplish that goal, SB proposes reasonable narrowing of the case that will allow the parties to ready the matter for trial quickly.

SB recognizes that further coordination among the parties to the MDL may be necessary as the case progresses. But the initial work SB proposes to undertake in this matter can and should be done now between SB and Regeneron, so that the parties can proceed to trial as quickly as possible. Moreover, Regeneron cannot claim to be burdened by the start of discovery or by an expedited schedule, given it has and is benefiting from temporary relief that has kept SB off the market for nine months already.

As the Fourth Circuit has advised, a “preliminary injunction is not permanent and does not determine the outcome on the merits,” and thus after an injunction issues, the district court should “proceed to hear the merits without undue delay, recognizing the importance of the interests of all parties which remain at stake.” *Faulkner*, 10 F.3d at 234; *see also Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) (approving how the district court “expedited [the] case and moved with appropriate speed towards a final disposition” after granting a preliminary injunction). That is because “[t]he best way to minimize the harm from granting the injunction is to proceed to trial on an expedited basis.” *Ortho McNeil Pharm., Inc. v. Barr Lab ’ys, Inc.*, No. CIV.A.03-4678SRC, 2009 WL 2182665, at *11 (D.N.J. July 22, 2009). Continuing further without a scheduling order from the Court would result in a *de facto* stay of the proceedings, subjecting SB “to unfair and undesirable delay in reaching final resolution.” *Procter & Gamble Co. v. Kraft Foods Glob., Inc.*, 549 F.3d 842, 849 (Fed. Cir. 2008).

SB therefore respectfully requests that the Court enter the schedule attached hereto in the above-captioned matters or, in the alternative, convene a status conference on an expedited basis.

Dated: February 3, 2025

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Ltd. appearing for the limited purpose of
contesting jurisdiction*

CERTIFICATE OF SERVICE

I hereby certify that on February 3, 2025, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

/s/ Sandra K. Law

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EXHIBIT A

Event	SB's Proposed Deadline
Opening of discovery, including third party	As soon as schedule is entered
Rule 26(a) initial disclosures	Fourteen (14) days after schedule is entered
Regeneron to narrow total number of asserted claims to no more than 20 claims from no more than five patents	March 3, 2025
Exchange of proposed claim terms for construction	April 1, 2025
Exchange of proposed constructions and intrinsic support	April 15, 2025
Submission of joint claim construction chart	April 29, 2025
Opening <i>Markman</i> briefs	May 20, 2025
Responsive <i>Markman</i> briefs	June 10, 2025
<i>Markman</i> hearing	Week of July 14, 2025, subject to the Court's availability
Substantial completion of document production	July 15, 2025
Deadline to amend pleadings	July 29, 2025
Close of fact discovery	September 9, 2025
Regeneron to narrow total number of asserted claims to no more than 15 claims from no more than four patents	September 16, 2025
Opening expert reports on issues for which the party bears the burden	October 21, 2025
Responsive expert reports	November 25, 2025
Reply expert reports	December 16, 2025
Close of expert discovery	January 30, 2026
Regeneron to narrow total number of claims asserted to no more than 10 claims from no more than three patents	February 10, 2026
Motions for summary judgment (if any)	March 3, 2026
Motions <i>in limine</i> and <i>Daubert</i> motions	March 3, 2026
Proposed Joint Pretrial Order	March 17, 2026