

**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:
Nos. 1:23-cv-94-TSK and 1:23-cv-106-TSK**

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

Plaintiff Regeneron Pharmaceuticals, Inc. opposes the motion for entry of a scheduling order or, in the alternative, a status conference, filed by Samsung Bioepis Co., Ltd. (“SB”). No. 24-md-03103, ECF 478 (“Mot.”). SB’s request to enter a schedule applicable to only one of the six cases constituting this multidistrict litigation (“MDL”) undermines the very efficiency gains for which this MDL was instituted. Furthermore, SB’s proposed schedule improperly attempts to force Regeneron to abandon, immediately and unilaterally, the vast majority of its asserted patents before discovery has even begun. The court should reject SB’s piecemeal approach and deny its motion.

I. BACKGROUND

As the Court is aware, this MDL concerns Eylea (aflibercept), Regeneron’s groundbreaking ophthalmology medicine that has saved the vision of tens of thousands of patients since its introduction in 2011. A number of pharmaceutical companies are attempting to market “biosimilar” copies of Eylea before the expiry of Regeneron’s patents protecting various aspects of the medicine’s manufacture, formulation, and use. Regeneron has filed patent infringement suits against six such companies or groups of companies, all of which are part of the same MDL:

(1) Mylan Pharmaceuticals Inc. and Biocon Biologics Inc.; (2) Celltrion, Inc.; (3) SB; (4) Formycon AG; (5) Amgen, Inc.; and (6) Sandoz, Inc. The United States Judicial Panel on Multidistrict Litigation created this MDL (over SB’s objection) to “promote the just and efficient conduct of this litigation,” “preserve judicial resources,” and “serve the convenience of the parties and witnesses” in view of the many “common questions of fact” presented in the various member cases. ECF 1 at 1, 3.¹

Regeneron last year sought to enjoin the launch of five of these biosimilars, and this Court ultimately entered four injunctions while denying the fifth, detailing its conclusions in over 700 pages of written opinions. ECF 188, ECF 194, ECF 247, ECF 248, ECF 352. SB was among the four parties enjoined by this Court. The Court explained, *inter alia*, that Regeneron was likely to succeed in proving that SB’s marketing of its proposed biosimilar product would infringe at least nine claims of U.S. Patent No. 11,084,865, that SB had not shown there to be substantial questions about the validity of these claims, and that “any manufacture, importation, or commercialization” of SB’s biosimilar before the expiry of the ’865 patent on June 14, 2027 would cause Regeneron irreparable harm. ECF 194 at 178. The United States Court of Appeals for the Federal Circuit recently affirmed the Court’s preliminary injunction of SB in a precedential decision issued on January 29. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2025 WL 321637 (Fed. Cir. Jan. 29, 2025). The Federal Circuit also affirmed the Court’s preliminary injunction of Formycon that same day. *Regeneron Pharm., Inc. v. Mylan Pharm. Inc.*, 2025 WL 324288 (Fed. Cir. Jan. 29, 2025). The remaining three appeals—in the Mylan, Celltrion, and Amgen matters—have been fully briefed and argued and await the Federal Circuit’s decision.

¹ All docket entry citations herein are to entries from the docket for MDL No. 1:24-md-03103-TSK.

II. ARGUMENT

A. SB's Piecemeal Scheduling Approach Should Be Rejected.

With its own appeal resolved,² SB now appears eager to proceed with the next phase of its litigation with Regeneron. But SB ignores that three of the six cases in this MDL remain on appeal, and the forthcoming Federal Circuit decisions will dictate the scope of further MDL proceedings. In urging a separate schedule for its case, SB fails to acknowledge the relevance of the unresolved appeals and the continuing “common questions of fact” and justice and efficiency concerns that the JPML recognized in ordering the coordination or consolidation of these cases. Of the 65 patents asserted among the operative complaints, 46 are at issue in more than one of the six cases, and 26 are asserted in three or more of those six cases.³ SB’s backdoor request that this Court, in effect, dismantle the MDL because its appeal happens to have been decided first (alongside Formycon’s) ignores those underlying concerns.⁴ It would risk inconsistent rulings and be inefficient for this Court, the parties, and witnesses to proceed with the SB litigation on one schedule while the remaining cases trail behind on separate tracks. The Mylan, Celltrion, and Amgen appeals all were argued within about two months of the SB and Formycon appeals and are

² SB and/or Formycon may petition for panel or en banc rehearing by February 28, 2025. Fed. Cir. R. 40(f)(1). Neither SB nor Formycon has indicated whether it will seek rehearing. Absent a petition, the Federal Circuit will issue its mandate approximately on March 7, 2025.

³ Regeneron has been working to prepare these cases for continued litigation following resolution of the appeals, including by filing amended complaints in several of the actions. These amended complaints have attempted to better focus the disputes by withdrawing infringement claims as to various patents while also asserting additional infringement claims as to patents that issued during the pendency of these cases. In recent months, Regeneron has filed amended complaints in the Celltrion, Formycon, and SB matters, ECF 430, ECF 441, ECF 445, and is presently conferring with Amgen and Mylan regarding amended complaints in those cases.

⁴ In its bid to separate its case from the others in this MDL, SB does not even mention that Formycon’s appeal was decided on the same day as its own.

expected to be resolved soon. When that occurs, Regeneron agrees the parties should promptly seek a status conference to address, *inter alia*, an appropriate schedule for the next phase of this MDL.

SB “notes” Rule 16’s statement that judges “must issue the scheduling order as soon as practicable, but unless the judge finds good cause for delay, the judge must issue it 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(b)(2); *see also* Mot. at 2. SB, however, does not go so far as to suggest the Court somehow has violated Rule 16, and for good reason—it is not currently “practicable” to issue a scheduling order while three of the six MDL cases remain on appeal, and ample “good cause” exists for waiting to issue such an order in view of the recognized justice and efficiency interests in consolidating or coordinating these MDL cases. SB’s duplicative approach would require multiple proceedings addressing the same patents commonly asserted among the MDL cases as well as numerous overlapping factual and legal questions. The Court has broad discretion in such matters given its “inherent authority to manage [its] docket[] and courtroom[] with a view toward the efficient and expedient resolution of cases.” *Adbul-Mumit v. Alexandria Hyundai, LLC*, 896 F.3d 278, 292 (4th Cir. 2018) (quoting *Dietz v. Bouldin.*, 579 U.S. 40, 47 (2016)).

SB’s sudden urgency is not justified, as the ’865 patent does not expire for more than two years. SB’s claims about the purported harm it has suffered because of the Court’s affirmed injunction ring hollow. The Biogen relationship that SB insinuates was somehow damaged by the injunction, Mot. at 1, had been in doubt for years before this case was even filed—Biogen jettisoned its nearly 50% share of SB in 2022, Ex. A, and in 2023 announced that it was broadly “evaluating strategic options” for its disappointing biosimilar business, Ex. B. And SB’s

complaints about losing its supposed “first-mover advantage” ignore that Mylan, not SB, was the first to seek approval for a biosimilar aflibercept product, and both companies’ products were approved on the same day. Mot. at 1; Ex. C.

B. SB’s Proposed Schedule Improperly Requires Regeneron to Withdraw Asserted Patents Unilaterally Before Discovery.

While the aim of achieving “just and efficient conduct of this litigation” alone is sufficient to reject SB’s tacit bid to unwind the JPML’s order, SB’s motion suffers from another flaw. In its effort to secure a separate, fast track for its own case while others remain on appeal, SB proposes a schedule that would require Regeneron “to narrow [the] total number of asserted claims to no more than 20 claims from no more than five patents” *in under two weeks*, with no discovery or claim construction. ECF 478-1 at 1; *see also* Mot. at 2.

SB’s effort to force Regeneron to play Russian roulette with its property rights is unfair and unlawful. While Regeneron certainly intends to narrow its case, reciprocally with Defendants narrowing their defenses, it cannot reasonably do so before it obtains discovery from SB that is relevant to infringement and the Court has construed the meaning of the patent claims.⁵ “Patent owners possess presumptively valid property rights which convey the right to exclude others from practicing the claims in their patents,” and the “property right conveyed by a patent has constitutional underpinnings.” *See Kilopass Tech., Inc. v. Sidense Corp.*, 738 F.3d 1302, 1317 (Fed. Cir. 2013) (citing U.S. Const. art. I, § 8, cl. 8). Requiring a patentee to forgo assertion of unique patent claims before obtaining sufficient discovery and rulings as to the meaning of those claims violates the patentee’s due process rights. *See In re Katz Interactive Call Processing*

⁵ SB has taken the position that it is under no obligation to respond to discovery requests beyond the narrow requests Regeneron served in connection with its preliminary injunction motions until those motions are fully resolved. Ex. D.

Patent, 639 F.3d 1303, 1312-13 (Fed. Cir. 2011). The Federal Circuit has warned that “a claim selection order could come too early in the discovery process, denying the plaintiff 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.” *Id.* at 1312, n.9. SB’s proposal would do precisely that, forcing Regeneron to reduce blindly its 42 distinct patented property rights (containing 895 claims) to only twenty claims from just five patents without the benefit of discovery from SB on those patents or any commensurate narrowing of SB’s own defenses. *See Impossible Foods Inc. v. Motif Foodworks, Inc.*, 2024 WL 3742229, at *3 (D. Del. July 26, 2024) (Bryson, J.) (“[T]he case narrowing procedure in the scheduling order invited [Plaintiff] to assert only the claims it believed to be strongest. In making that determination, [Plaintiff] was entitled to decide which claims it believed to be the strongest with the benefit of knowing what invalidity positions Defendants would be taking.”).

III. CONCLUSION

For the foregoing reasons, Regeneron respectfully requests that the Court deny SB’s motion and convene a status conference following resolution of all the pending appeals in this MDL action.

Date: February 18, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on February 18, 2025, I electronically filed the foregoing with the Court. Counsel of record for all parties will be served by the Court's CM/ECF system.

/s/ Steven R. Ruby

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