

**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:**

REGENERON PHARMACEUTICALS, INC.,

No. 1:23-cv-97-TSK

Plaintiff,

v.

FORMYCON AG,

Defendant.

**DEFENDANT FORMYCON AG'S REPLY IN SUPPORT OF ITS MOTION TO  
PARTIALLY ADOPT AND JOIN SAMSUNG BIOEPIS, CO., LTD.'S MOTION FOR  
ENTRY OF SCHEDULING ORDER PURSUANT TO RULE 16 OR, IN THE  
ALTERNATIVE, A STATUS CONFERENCE**

The last time the Court spoke to the parties was back in May 2024. A lot has happened since then, to say the least, including Amgen’s US launch of its EYLEA® biosimilar product.<sup>1</sup> Yet Regeneron opposes having a status conference until after “resolution of the pending appeals in this MDL action.” (24-md-3103, Dkt. 496 at 7.) Of course it does; the preliminary injunction currently in place becomes *de facto* a permanent injunction if a merits decision is not reached by June 14, 2027 (the expiration date of the ’865 Patent).

This case is well-poised to move forward, especially now that all appeals on the preliminary injunction proceedings are complete and, thus, all similarly situated parties in this MDL are ready to proceed in the district court. Just today, the Federal Circuit resolved the Amgen appeal. (*See id.*, Dkt. 498 (affirming this Court’s decision to deny Regeneron’s motion for preliminary injunction against Amgen).) Though the Mylan appeal is still pending, that case is in an entirely different posture—Mylan has already gone through a full trial on the merits. Furthermore, it is not known when the Mylan appeal will be resolved. The oral argument in the Mylan appeal occurred just over a month ago on February 7, 2025. And even after the Federal Circuit renders its decision, the mandate will not issue for more than a month. (*See* FED. R. APP. P. 41(b) (“The court’s mandate must issue 7 days after the time to file a petition for rehearing expires, or 7 days after entry of an order denying a timely petition for panel rehearing, petition for rehearing *en banc*, or motion for stay of mandate, whichever is later.”).)

Moreover, less developed cases should not delay resolution of Regeneron’s claims against Formycon. (*See* 24-md-3103, Dkt. 1 at 3 (noting later filed cases “may trail those in the [earlier

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<sup>1</sup> *See Biogen Inc. v. Sandoz Inc.*, C.A. No. 22-cv-1190-GBW, 2023 WL 7130655, at \*2 (D. Del. June 29, 2023) (“A party seeking a preliminary injunction must establish that it is likely to suffer irreparable harm if the preliminary injunction is not granted and there is a causal nexus between the alleged infringement and the alleged harm.”) (*quoting Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017)).

filed] West Virginia actions” and “still . . . provide efficiencies for the parties and preserve judicial resources”).) For example, Regeneron’s attempt to put the Formycon and Sandoz cases on equal footing is not warranted. Formycon participated in the patent dance, serving its BLA and exchanging contentions with Regeneron, and engaged in preliminary injunction proceedings involving 3 months of discovery, 9 depositions, and the exchange of over 30,000 pages of materials. Sandoz has apparently not even provided its BLA. (*See* 24-cv-85, Dkt. 1, ¶ 4.)

Like the denosumab cases, which were proceeding on separate tracks prior to MDL, these cases can be efficiently managed to prevent prejudicial delay. Regardless of whether the denosumab cases continue on separate case tracks, a single judge was successfully managing multiple biosimilar-related cases at once. (24-md-3103, Dkt. 484 at 2-4.) Regeneron provides no reason why this Court cannot do the same.

Moreover, any further delay in moving this case forward increases the risk that new cases are added to the MDL prior to “resolution of the pending appeals.” After all, at least one additional biosimilar applicant has announced submission of an aflibercept BLA in 2025, and at least two more biosimilars are in development. (*See id.* at 4.)

Regeneron filed its case against Formycon over fifteen months ago. Moving forward now is just and proper. Formycon respectfully requests that the Court schedule a status conference without waiting for the pending appeal to resolve.

Dated: March 14, 2025

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned attorney hereby certifies that on March 14, 2025, I caused a true and correct copy of the foregoing *DEFENDANT FORMYCON AG'S REPLY IN SUPPORT OF ITS MOTION TO PARTIALLY ADOPT AND JOIN SAMSUNG BIOEPIS, CO., LTD.'S MOTION FOR ENTRY OF SCHEDULING ORDER PURSUANT TO RULE 16 OR, IN THE ALTERNATIVE, A STATUS CONFERENCE* to be filed via the Court's CM/ECF electronic filing system, thereby sending notice of the filing to all CM/ECF-registered counsel of record for Plaintiff.

/s/ M. David Griffith, Jr.  
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