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 SUBMISSION IN RESPONSE TO MAY 20, 2024 ORDER

On May 20, 2024, the Court ordered the parties to file submissions of no more than 20 pages "indicating which matters are appropriate for collective pretrial consideration and disposition while the case is designated as an MDL." ECF No. 112. The parties conferred on May 28, 2024, and reached substantial agreement with respect to these issues, as set forth below. The remaining areas of disagreement are provided in the below party-specific sections. Consistent with the Court's Order, the parties have also attached to this submission all filings submitted to the Judicial Panel for Multidistrict Litigation.

I. The Parties' Proposal

The member cases of MDL No. 3103 are currently consolidated for pretrial proceedings. The parties agree that those pretrial proceedings should include (1) resolution of all pending personal jurisdictional motions, (2) the resolution of all motions for preliminary injunction or temporary restraining order; (3) the completion of fact and expert discovery, including the adjudication of any related motion practice; (4) resolution of all claim construction ("*Markman*") proceedings, (5) case management to administer the proceeding by ordering, for example, case narrowing as appropriate; and (6) resolution of dispositive motions.

The parties propose that the Court schedule bimonthly conferences (*i.e.*, every two months) to address the conduct and status of the pretrial proceedings. Such conferences are recommended by Fed. Judicial Ctr., Manual for Complex Litigation (4th ed., 2004) at Section 11.22. The parties propose submitting joint, non-argumentative status reports at least one week prior to each scheduled conference that include a progress report and a proposed agenda of items to be addressed at the conference. If there are no agenda items to address, then the conference could be canceled at the Court's discretion.

The parties suggest that it is not necessary at this time for the court to determine whether it will decide other pretrial motions, and suggest that issue be addressed at a bi-monthly conference after completion of discovery.

The parties also agree that any case for which the transferor court is not the Northern District of West Virginia—including the "Amgen Case" (Case No. 24-cv-39-TSK) and any case dismissed or transferred to another venue for lack of personal jurisdiction—may be remanded for trial before a final pretrial order is entered and a final pretrial conference is held in all member cases remaining in the Northern District of West Virginia.

Mylan/Biocon's Position

Biocon Biologics, Inc. ("Biocon") and Mylan Pharmaceuticals Inc. ("Mylan") consent to consolidation and collective disposition of the member cases for all pretrial proceedings as noted above, to the extent that the Court is inclined to enter a schedule with a trial in summer/fall of 2025 as requested by one or more of the MDL Defendants. However, as noted in their May 10, 2024 position statement, Biocon and Mylan are uniquely situated compared to the other MDL Defendants, so to the extent the Court is inclined to enter Regeneron's requested schedule (July 2026 trial) with regard to the other Defendants, then Biocon and Mylan would request a separate

track, and entry of the schedule proposed by Biocon and Mylan in their May 10 submission, which contemplates trial in September 2025, or as close to that proposed trial date as the Court's schedule allows. Separate tracks are common in MDL proceedings. *See, e.g., In re: Nat'l Prescription Opiate Litig.*, MDL No. 2804, 1:17-md-02804, Dkt. 232, at 6-8 (N.D., Ohio Apr. 11, 2018) (setting different scheduling tracks for differently positioned cases); *see also, e.g.*, *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, MDL No. 2785, 2019 WL 294803, at *6 (D. Kan. Jan. 23, 2019); *Fed. Ins. Co. v. 3M Co.*, Case No. 21-cv-02093, 642 F. Supp. 3d 882, 895-96 (D. Minn. Nov. 23, 2022) (citing *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005)). Indeed, separate tracks have already been implemented in this MDL. (*See, e.g.*, MDL Dkts. 136, 144 (ordering any injunction against Amgen to proceed on a different briefing schedule than the other Defendants' schedules)).

A separate track is particularly warranted here, where Biocon and Mylan already have completed an entire litigation, including *Markman*, fact discovery, expert discovery, and trial, on a set of Regeneron's selected patents.

However, even in the event of separate tracks, Biocon and Mylan are not opposed to consolidation and collective disposition of matters common across all MDL cases, including with regard to, to the extent possible, holding combined *Markman* proceedings, coordinating with other Defendants regarding depositions, matters relating to patent invalidity, and other discovery issues.

Biocon and Mylan do not have a position as to when the other Defendants' cases are remanded to other jurisdictions for trial.

Regeneron's Response

Biocon/Mylan (collectively, "Biocon") reprise their argument –rejected by this Court in February (No. 1:22-CV-61, Dkt. 698) and by the Judicial Panel on Multidistrict Litigation in April (No. 24-md-3103, Dkt. 1) – that they are uniquely positioned and their case should proceed on a separate, faster track than co-pending cases against other MDL Defendants. There is no basis for Biocon's demand. As adjudged infringers of USP No. 11,084,865 (the "'865 patent"), which does not expire until June 2027, there is no reason to expedite trial of the remaining patents against Biocon. Biocon's proposal would create inefficiencies for the Court and the parties, needlessly complicate proceedings, and introduce opportunities for inconsistent or revisited rulings.

First, a large number of the remaining patents in the Biocon case also are asserted against one or more of the additional MDL Defendants. Indeed, the number of overlapping patents will only increase before these cases begin in earnest, as Regeneron may file suit against Biocon on additional patents pursuant to 42 USC § 262(*l*)(7) (governing patents issuing after certain stages of the patent dance) to bring that case current with the cases against other Defendants filed at a later date (and thus after additional patents had issued). Biocon suggests that Regeneron previously represented that trial on a second wave of patents would not be necessary. Not so. Regeneron stated that it "d[id] not know exactly what will happen" with the remaining patents, and explained that "[i]f we prevail on these patents that we're proposing to move forward with now . . . then it's very unlikely that we would feel the need to move forward again with respect to those other patents." No. 22-cv-61-TSK, Dkt. 90 at 4-11. While Regeneron *did* prevail with respect to the '865 patent, it did not receive a favorable judgment on later-expiring patents from the first round of litigation (USP Nos. 10,888,601, 11,253,572, and 11,104,715). Thus, Biocon's

infringement of additional patents remains an important consideration. Nor can Biocon unilaterally decree trial on the remaining patents to be unnecessary. "Regeneron does not agree that its remaining, presumptively valid patents should be dismissed with a wave of the hand." No. 22-cv-61-TSK, Dkt. 697 at 6-7 (opposing Biocon's earlier motion for expedited trial). Regardless, the handful of patents on which Biocon has already obtained a judgment do not outweigh the large number of common patents that remain to be adjudicated against Biocon and all other Defendants. Nor do Biocon's cited cases justify separate tracks on these facts.[1]

Second, Biocon's premise that it is differently situated because it already has "completed an entire litigation, including *Markman*, fact discovery, expert discovery, and trial," ignores the substantial amount of work that remains to be accomplished not only because of the new patents to be addressed but also because of the narrow scope of the initial phase of the Biocon litigation. That first phase was limited by the particular issues and parties involved, and the remaining patents present new and distinct issues. *See* No. 22-cv-61-TSK, Dkt. 697 at 6-7 (providing examples). Furthermore, Biocon was not joined as a party until the eve of trial following its acquisition of Mylan's biosimilars business, and Regeneron has had only limited opportunities to obtain discovery from Biocon in the context of the present, expedited injunction proceedings. Much work—including additional fact discovery, claim construction, and expert discovery—remains to be done.

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[1] *See, e.g., In re: Nat'l Prescription Opiate Litig.*, MDL No. 2804, 1:17-md-02804, Dkt. 232, at 1 (N.D., Ohio Apr. 11, 2018) (creating separate "settlement track" and "litigation track" because parties stated such tracks would make settlement more likely); *see also, e.g.*, *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, MDL No. 2785, 2019 WL 294803, at *2 (D. Kan. Jan. 23, 2019) (allowing *Sanofi* case to proceed on separate track than consumer class cases because Sanofi, as competitor of defendant, filed *Sanofi* case "only for itself, and not on behalf of any other plaintiffs or putative class members," and did not seek class certification); *Fed. Ins. Co. v. 3M Co.*, Case No. 21-cv-02093, 642 F. Supp. 3d 882, 895-96 (D. Minn. Nov. 23, 2022) (stating merely that MDL courts can create separate tracks where appropriate).

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