IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., *Plaintiff*, v. MYLAN PHARMACEUTICALS INC., and BIOCON BIOLOGICS INC., *Defendants*.	Case No. 1:22-cv-00061-TSK

REGENERON'S OPPOSITION TO DEFENDANTS' EXPEDITED MOTION FOR ENTRY OF A SCHEDULING ORDER

Plaintiff Regeneron hereby opposes the "Expedited Motion for Entry of a Scheduling Order" (D.I. 691) ("Motion") filed by Defendants Mylan Pharmaceuticals, Inc. and Biocon Biologics Inc. (collectively, "Defendants" or "Biocon"). Biocon's motion is baseless.

I. BACKGROUND

On December 27, 2023, this Court issued an opinion holding that Biocon will infringe Regeneron's U.S. Patent No. 11,084,865 ("the '865 patent"), and that Biocon failed to prove the '865 patent was invalid. D.I. 664. The '865 patent does not expire until June 2027.

Plainly, Biocon is aggrieved by that result, and its response constitutes the legal equivalent of a temper tantrum—a cathartic exercise without basis in efficiency or logic. Before the December 27th opinion issued, Biocon advised this Court there was no need even for a status conference, let alone another expedited trial. D.I. 652-1 ("Defendants believe there is no immediate need for a status conference."). Now, Biocon *demands* a scheduling order that, if granted, could result in trial on more than a dozen patents in a "second wave" of litigation this October. Motion (D.I. 691) at 6, 9; Biocon's Proposed Schedule (D.I. 691-1) at 2. No facts or

circumstances support Biocon's extraordinary proposal (a proposal that Regeneron saw for the first time upon service of Biocon's motion). Phase I of this case is not "over," Mot. at 1; permanent injunction proceedings against Biocon with respect to the '865 patent likely are imminent, and an appeal from this Court's decision is a certainty. Equity does not demand an expedited schedule, Mot. at 2, 5; unlike Phase I, there is no rush to meet a statutory deadline. Biocon does not lack certainty as to when it may commercialize its infringing biosimilar product, Mot. at 4-6; Biocon already has the certainty it requires for years to come—it is an adjudged infringer of a patent that does not expire until June 2027 and will not be able to commercialize its product until at least that time. Instead, coordination of Biocon's case with cases against other Defendants on the same patents will promote efficiency; Biocon's self-professed status "in front of other biosimilar applicants," Mot. at 1 n.1, 6-9, is irrelevant in view of this Court's decision that any effort to *market* its biosimilar product would violate Regeneron's patent rights. Finally, Regeneron would be prejudiced by Biocon's requested relief in view of co-pending, preliminary injunction proceedings. Neither this Court nor Regeneron should be forced to adjudicate more than a dozen patents at breakneck speed when the existing decision is sufficient to provide at least three years of repose.

II. ARGUMENT

Biocon's brief elides the only fact that matters: its aflibercept product will infringe the '865 patent until that patent expires in June 2027. Biocon recognizes—in discussions with Plaintiffs, if not its Motion—that unless it reverses through appeal this Court's December 27th decision with respect to the '865 patent (and at the same time avoid reversal of the Court's decision as to the validity of the '572 and '601 patents), it cannot market its product until 2027 *at the earliest*. Biocon's brief thus suggests, *sub silencio*, that reversal of this Court's 300-page, fact-intensive opinion is a foregone conclusion, making Regeneron's additional patents the only

thing standing between it and the marketplace. Not so. In view of this Court's December opinion, there is simply no urgency to adjudicate additional patents by October 2024, or for that matter any time before June 2027. Notwithstanding Biocon's tit-for-tat desire to impose an expedited schedule on Regeneron, no useful end could be served by such an effort, especially in light of the co-pending injunction proceedings against Formycon, Celltrion, and Samsung Bioepis, (soon to be joined by Biocon, for reasons explained below). Pursuant to the schedule that has governed this case from the outset, Phase II of this litigation should proceed when Phase I concludes. At that juncture, the parties and the Court can consider the precise schedule for Phase II, including the appropriate extent of coordination with other cases then pending in this district (including through multi-district litigation).

A. Phase I of this Case is Not Over

Phase II of this litigation should follow completion of Phase I. Notwithstanding Biocon's exhortations to the contrary, Mot. at 2, Phase I is *not* over. The Federal Circuit will review this Court's decision upon entry of a Rule 54(b) judgment. And before entry of such a judgment is possible, Biocon may force Regeneron to jump through the hoops of a permanent injunction proceeding. The parties should focus their resources on those imminent disputes, rather than rushing to meet a nonexistent deadline.

After this Court's decision issued in December, Regeneron promptly sought to confer with Biocon regarding an appellate schedule, in the hopes of obtaining a Federal Circuit decision—and the attendant statutory injunction—by May 2024. Regeneron was confident that a May 2024 Federal Circuit decision was obtainable, but only with Biocon's cooperation, including because Biocon controlled timing of filing a notice of appeal to initiate appellate proceedings. Unfortunately, that cooperation was not forthcoming. Biocon insisted that there was no expedited schedule (or at least no schedule to which it would agree) that could result in a

Federal Circuit judgment before Regeneron's regulatory exclusivity expired, and insisted on including additional counts from Regeneron's complaint in any Rule 54(b) judgment that would trigger the right to appeal, in addition to those tried last June. Thus, instead of speeding toward appellate review as planned, the parties are mired in disputes regarding the scope of the judgment from which any appeal can be taken.

Accordingly, Regeneron sought confirmation that Biocon did not intend to flout this Court's judgment by marketing its infringing product before the Federal Circuit mandate issued, in hopes of sparing the parties and the Court unnecessary permanent injunction proceedings. Biocon has acknowledged repeatedly that it cannot commercialize its Eylea® biosimilar in view of this Court's decision as to the '865 patent, and the parties therefore have attempted to negotiate a stipulation to maintain the status quo pending appeal. Unfortunately, although Biocon acknowledges that such a stipulation preventing commercialization of its biosimilar product before the appeal is resolved is appropriate, it has (thus far) insisted on including caveats and exceptions that are not acceptable to Regeneron. The parties therefore have not yet presented such a stipulation for the Court's consideration.

One of two things will happen next. One possibility is that Biocon will file a joint stipulation effectively reflecting what it has all but told Regeneron—that absent Federal Circuit reversal, Biocon cannot and will not market its biosimilar aflibercept product before either expiry of the '865 patent. In that case, the parties will seek a Rule 54(b) judgment that permits appeal, and Phase I of this case will conclude when an appellate judgment issues (or after the conduct of any remand proceedings ordered by the court of appeals).

The other possibility is that Biocon will not file such a stipulation not to commercialize its product, thereby forcing Regeneron to put itself and this Court through the formalities of

seeking a permanent injunction before May 18, 2024. Those proceedings overlap substantially with the preliminary injunction proceedings the Court has scheduled, and Regeneron submits that it would be most efficient to adjudicate the permanent injunction request against Biocon on the same schedule. *See* Ex. A (proposing injunction schedule against Biocon). Whatever the schedule for those permanent injunction proceedings, the parties cannot even seek an appealable Rule 54(b) judgment until entry of that injunction. *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1365 (Fed. Cir. 2007); *Creative Compounds, LLC v. Starmark Labs.*, No. 2009-1595, 2009 WL 5171738, at *1 (Fed. Cir. Dec. 30, 2009) ("Because there is a pending claim for injunctive relief, the case is not final except for an accounting. Thus, we must dismiss this appeal."); *see also Imprenta Servs., Inc. v. Karll*, No. 2022-2122, 2023 WL 1094326, at *1 (Fed. Cir. Jan. 30, 2023); *Natron Corp. v. Borg Indak, Inc.*, No. 2012-1292, 2012 WL 10242279, at *1 (Fed. Cir. Aug. 3, 2012). Phase I is far from over.

B. Biocon Already Has Certainty: Its Product Will Infringe Until 2027

As Phase I marches forward, there is no pressing need to allow Phase II to jump the queue. Simply put, Biocon does not lack "patent certainty." *Contra* Mot. 3. Biocon has the certainty it requested; it just does not like the answer it received: Biocon's aflibercept product infringes Regeneron's '865 patent. D.I. 665. That patent does not expire until June 2027. No patent *un*certainty could affect Biocon for at least the next three years.

Biocon's "equitable" demands for expedition are predicated on two faulty principles: *First*, Biocon suggests that because it was "subjected" to expedited proceedings before, Regeneron should endure the same now. Mot. 2; *see also* Mot. 5 ("Now the shoe is on the other foot."). *Second*, Biocon asserts that the Court should behave as though every single one of the following events will occur, and occur imminently: (1) the Federal Circuit will return a decision no later than October, despite the fact that no operable notice of appeal has been filed and no

request to expedite the appeal has been filed, let alone granted; (2) the Federal Circuit will reverse this Court's decision on the '865 patent; (3) the Federal Circuit will not reverse this Court's decision regarding invalidity of the '601 and '572 patents; *and* (4) every single asserted claim of each of Regeneron's unadjudicated patents will be adjudged not infringed and/or invalid. Biocon's first argument elevates its desire for revenge over any consideration of logic or efficiency; the second is simply a pipe dream.

1. Scheduling "Revenge" Does Not Justify Wasting Court Resources

No "eye for an eye" scheduling justice is called for here. Regeneron sought and received an expedited trial because a statutory remedy was available to it for a limited time. D.I. 7 at 1. Recognizing that it was seeking an unusually fast schedule, Regeneron promised to limit the case in a manner befitting that schedule, D.I. 88 (limiting first phase of litigation six patents from three patent families); D.I. 174 at 4 n.1 (agreeing to limit trial to no more than twelve claims). Critically, in exchange for expedited proceedings, Regeneron also *agreed to forgo injunctive relief* on patents not asserted in Phase I. D.I. 90 at 24:9-16.

Biocon, on the other hand, now demands much, offers little, and has even less at stake. Biocon asserts that it is possible to resolve infringement and validity issues for more than a dozen patents in eight months, ostensibly because it arrogates to itself the power to adjudge Regeneron's property rights and deem the Phase II patents the "dregs" of Regeneron's portfolio. Mot. 5. Unsurprisingly, Biocon's proposal is short on specifics, making only vague references to "abbreviated" *Markman* proceedings (without acknowledging how many disparate patent families will be involved) and emphasizing the discovery that has already taken place (without grappling with the substantial discovery that has not yet occurred). Mot. 6. For avoidance of doubt, Regeneron does not agree that its remaining, presumptively valid patents should be dismissed with a wave of the hand, does not agree that the parties have completed "most" fact

discovery regarding those patents, and does not agree that expert discovery has concluded on the "core" claims of those patents.[1] Biocon is simply wrong on the facts.

For example, U.S. Patent No. 9,222,106 (D.I. 1-2) ("the '106 patent") is unrelated to any of the patents included in Phase I. None of its inventors was a document custodian in Phase I and none of its inventors was deposed. The claimed methods relate to how, precisely, the gene that encodes aflibercept is put into a host cell. Among other things, Regeneron would seek samples of Biocon's host cells so that they could be tested to determine precisely where Biocon inserted the gene encoding aflibercept. Biocon did not produce cell line samples in Phase I and none of the required genetic testing was done in Phase I, because none of these facts were relevant to Phase I's disputes.

Similarly, U.S. Patent No. 9,816,110 (D.I. 1-5) also is unrelated to any of the patents included in Phase I. None of its inventors was a document custodian in Phase I and none of its investors was deposed. It raises issues similar to those raised by the '106 patent, none of which was the subject of Phase I discovery.

These are just two examples of the claims and issues that remain as to which an expedited discovery period would be prejudicial and illogical.

2. There is No Need to Adjudicate More than A Dozen Patents Before October

Even were it possible to litigate a multitude of patents to judgment in the next eight months, there is simply no need to do so. As the facts stand, Biocon is an adjudged infringer of the '865 patent, and cannot market free of patent liability until at least 2027. In the unlikely

[1] Biocon is correct that Regeneron has disclaimed three patents asserted in its complaint, which will not be at issue in any subsequent litigation. The parties have also engaged in the Patent Dance on patents that issued to Regeneron too late to be included in the first wave of litigation; as the BPCIA contemplates, Regeneron may file suit on these patents as needed.

event the Federal Circuit reverses this Court's decision regarding the '865 patent (but not the '572 and '601 patents), Regeneron has already represented to this Court that it will not seek injunctive relief on any patent it did not assert in Phase I. D.I. 90 at 23:14-24, 24:9-16.

Biocon inveighs that it cannot obtain the "certainty" it desires before October, ostensibly on the basis that it views a decision of this Court as providing something short of certainty. Even were the parties to proceed on Biocon's proposed schedule, no appellate decision could be obtained on as-yet-unadjudicated patents by Biocon's arbitrary October date. To the contrary, there currently is no basis for Biocon's assertion it will obtain an appellate decision even on the '865, '572, and '601 patents by October. Mot. 6. Indeed, unless it reverses course and enters into a stipulation, Biocon cannot even initiate its appeal until after the Court issues a permanent injunction decision, presumably following the May 2, 2024 hearing. And even if it does obviate the need for injunctive proceedings, the status quo is that the parties agree the case is not yet ripe for appeal, despite efforts to negotiate an appealable judgment. D.I. 687 and 688.

In short, Biocon demands extraordinary efforts in pursuit of illusory relief. Biocon's "need" for a schedule is predicated on its assumption that this Court will be reversed (no later than a made-up date in October), and the objective of Biocon's schedule (adjudication of more than a dozen patents) will not change whether and when Biocon can launch its product if it *does* obtain a reversal. There is no reason to exhaust the parties' and Court's resources on the facts here.

C. The Remainder of Biocon's Case Should Be Coordinated With Other Defendants

Regeneron respectfully submits that if permanent injunction proceedings are necessary against Biocon, they can be efficiently coordinated with the preliminary injunction proceedings underway against Formycon, Celltrion, and Bioepis, and has attached a schedule to that effect as

Exhibit A. There is no longer any need, of course, to assess likelihood of success on the merits—the merits against Biocon have been decided on a complete record. The "irreparable harm" and balance of hardship inquiries in the injunction proceedings, however, will be common across all defendants. To maximize efficiency, Regeneron intends to file its motion for permanent injunction against Biocon on the same day it files motions seeking preliminary injunctions against Formycon, Celltrion, and Bioepis (*i.e.*, February 22, 2024).[2] *See* Ex. A.

Looking beyond those immediate proceedings, there is no reason that Phase II of Biocon's case should not proceed on the same schedule as three other cases sharing numerous patents in common. It would be inefficient in the extreme for this Court to address the same issues on the same patents regarding biosimilar versions of Eylea® at two different trials, particularly when Biocon is not differently situated as to those portions of the case. Regeneron has already produced to Formycon, Celltrion, and Bioepis the patent-related documents it produced to Biocon, and the parties will be well positioned to proceed apace after injunctive proceedings have concluded. Furthermore, this Court has already decided not to allow the various spurious motions to dismiss Formycon, Celltrion, and Bioepis filed in the other three actions to delay resolution of their merits, so there is no reason to believe Biocon "will be mired in jurisdictional fights for months before even commencing litigation proper." Mot. 6; *Regeneron Pharms, Inc. v. Formycon AG*, 23-cv-97, D.I. 45 (N. D. W. Va. January 9, 2024) (setting schedule for jurisdictional briefing in Formycon, Celltrion, and Bioepis cases). To the contrary, there is every reason to believe that after the May 2 hearing, Regeneron and all defendants can proceed expeditiously to litigation on the relevant patents, as well as any others

[2] Accordingly, on January 19, 2024, Regeneron served on Biocon a modest set of document requests relating to these inquiries. Biocon has not responded, even though all other defendants (Formycon, Celltrion, and Bioepis) have already made productions to this end.

asserted in the respective complaints. Finally, Biocon's assertion that the issues on the unadjudicated patents do not overlap with the other cases is simply unfounded. Regeneron has asserted a substantial number of relevant patents against each of Biocon, Formycon, Celltrion, and Bioepis. Biocon lacks *any* information whatsoever to support its sheer speculation that there are significant differences in the defendants' formulations or manufacturing processes that will create inefficiencies. Mot. 8-9. Each defendant seeks to market a biosimilar version of the same drug: Eylea®. More detail than that cannot accompany a public filing, and is not in Biocon's hands.

Of course, Biocon's *real* complaint is not one the Court can resolve: Biocon started the race first, but has now lost its pole position. Mot. 1 n.1, 6-9. Biocon's "advanced" status relative to other biosimilar applicants did indeed result in different treatment at the outset—Regeneron proceeded against Biocon to a trial on the merits before even filing suit against any of the other defendants. Biocon was, accordingly, the first party to achieve patent certainty. That effort resulted in a judgment of infringement. Asking this Court to pretend Biocon is *still* out "in front" of other biosimilar applicants defies credulity. Biocon may once have led the pack; it is now the first disqualified from the race. In view of the existing judgment against it, Biocon will not be prejudiced by proceeding on any unadjudicated patents in concert with Formycon, Celltrion, and Bioepis.

D. Regeneron Will Be Prejudiced by Biocon's Proposed Schedule

Regeneron would suffer enormous prejudice if forced to adjudicate more than a dozen patents in the next eight months. As this Court knows, Regeneron is in the midst of preliminary injunction proceedings against three other defendants, with opening papers due in less than three weeks. Those proceedings will move forward at a sprint until May 2, 2024, when the Court will hold a preliminary injunction hearing. The remarkable overlap between Biocon's proposed

schedule and the existing preliminary injunction schedule is, of course, no pure coincidence. It is bad enough that Biocon is likely to force the Court to adjudicate a motion for permanent injunction, rather than enter a stipulation confirming that Biocon will not commercialize its product, while preliminary injunction proceedings against Formycon, Celltrion, and Bioepis are underway. It would be truly unworkable to ask the Court to hold *Markman* proceedings, and for Regeneron to undertake fact discovery, on a schedule that conflicts with those proceedings at every turn. Biocon's demands are unreasonable, would needlessly overburden the court and prejudice Regeneron, and as described above, would not resolve any issue that could interfere with launch of Biocon's product in the unlikely event of a Federal Circuit reversal on the '865 patent (and only the '865 patent). The Court should reject Biocon's proposed schedule and adjudicate any additional patents after injunctive and appellate proceedings are complete.

III. CONCLUSION

For the foregoing reasons, Regeneron respectfully requests the Court deny Biocon's motion and enter the schedule attached as Exhibit A to govern any permanent injunction proceedings against Biocon.

Date: February 6, 2024

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 6th day of February 2024, the foregoing was filed using the Court's CM/ECF system, which will provide service to all counsel of record.

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REGENERON'S PROPOSED PERMANENT INJUNCTION SCHEDULE

Event	Deadline
Regeneron delivers targeted requests for production to Defendants (limited to issues relevant to injunction proceedigns)	January 19, 2024 [Completed]
Regeneron produces documents relevant to permanent injunction proceedings	Within two business days of entry of this order.
Defendants produces documents responsive to Regeneron's requests	February 15, 2024
Regeneron to file motion for permanent injunction and supportive memorandum	The later of February 22, 2024 or seven days after Defendants produce documents responsive to Regeneron's requests.
Depositions of any Regeneron declarants complete	March 13, 2024
Defendants file opposition to motion for permanent injunction	March 21, 2024
Deposition of Defendants' declarants complete	April 10, 2024
Regeneron files reply in support of permanent injunction	April 18, 2024

Hearing on Regeneron's motion for permanent injunction	May 2, 2024, at 10:00 a.m.
In-person status conference with lead counsel ahead of May 18, 2024 expiration of regulatory exclusivity	May 13, 2024, at 12:00 p.m.