

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

Civil Action No. 1:23-cv-00089

CELLTRION, INC.,

Defendant.

**DEFENDANT CELLTRION, INC.’S RESPONSE TO PLAINTIFF’S
EMERGENCY MOTION FOR ENTRY OF A SCHEDULE FOR PRELIMINARY
INJUNCTION PROCEEDINGS¹**

There are various issues with Regeneron Pharmaceuticals, Inc.’s (“Regeneron”) proposed schedule. *See* ECF No. 45.² Given the serious concerns about personal jurisdiction and venue in this action (a motion to dismiss on those grounds is forthcoming), this Court should allot time to hear those issues before setting a schedule for preliminary injunction proceedings. Such a path forward is even more appropriate in light of Regeneron’s disclosure at last week’s Scheduling Conference that it may sue additional defendant(s).

But even if this Court believes it should set preliminary injunction deadlines in addition to motion to dismiss deadlines, it should not adopt the schedule proposed by Regeneron. Among other things, Regeneron’s schedule puts the cart before the horse: it provides for discovery prior

¹ By filing this Response, as with its response to Regeneron’s other pre-service motion, *see* ECF No. 52, Celltrion makes only a special appearance before the Court. It does not waive any objections or defenses, including any of those identified in Rule 12 of the Federal Rules of Civil Procedure, and specifically objections and defenses based on the lack of personal jurisdiction and/or improper venue. *See* Fed. R. Civ. P. 12(b)(2) & (3). In its forthcoming motion to dismiss, Celltrion will address, among other matters, the lack of personal jurisdiction over it and improper venue in this matter.

² In the interest of judicial efficiency, Celltrion joins in and incorporates the positions taken by Formycon AG (“Formycon”) in its response to Regeneron’s motion filed in its parallel litigation against Formycon, *see* ECF No. 43, Case No. 1:23-cv-00097.

to the filing of its motion for preliminary injunction, which runs contrary to the governing statutory scheme and the practical reality of the compressed timeline here. *See* 42 U.S.C. § 262(l)(8)(C) (providing, under the Biologics Price Competition and Innovation Act, that expedited discovery may be available once (and if) a preliminary injunction has been sought).

Celltrion’s proposed schedule for preliminary injunction proceedings (to the extent the Court finds that a schedule is necessary at this time) is a more efficient path forward. Regeneron’s regulatory exclusivity over Eylea expires in May 2024. During the Scheduling Conference, Celltrion explained that it wishes to wrap up Regeneron’s potential preliminary injunction motion proceedings prior to that deadline. That is why Celltrion’s proposed schedule contemplates Regeneron filing its potential preliminary injunction motion early in this action (by January 17, 2024). That possible motion is the trigger for all of the necessary proceedings to follow. And Regeneron has had months to prepare that motion. To delay that filing by over a month from now — as proposed by Regeneron — does not make sense and will only put additional onus on the parties and this Court.

Celltrion’s proposed schedule also recognizes the reality of the compressed timeframe: it is not feasible to accomplish discovery, briefing, and an evidentiary hearing on Regeneron’s possible motion for preliminary injunction by May unless Regeneron narrows the patents and claims at issue at the outset and files its preliminary injunction motion soon. Patent-related discovery is voluminous. Indeed, Celltrion has already provided Regeneron with hundreds of thousands of pages of detailed technical information about its proposed product and manufacturing process during the “patent dance” and will provide Regeneron with more information today in the form of detailed contentions concerning non-infringement and invalidity of the 39 patents asserted in Regeneron’s complaint. Given that May is only four months away, a narrowing of Regeneron’s

patents and claims at the outset is necessary. Requiring Regeneron to file its motion promptly also cannot prejudice it, since Regeneron has had the detailed technical information about Celltrion's product and process for *over three months*.

It is also crucial that Regeneron file its motion promptly so that Celltrion can be given a fair opportunity to oppose that motion. If Regeneron is required to file its motion on January 17, it will have had almost four months to assemble its papers. Regeneron's proposed schedule would give Celltrion only one month to assemble an opposition to what will likely be a complex set of arguments supported by a multitude of fact and expert declarations. This would be patently unfair, counter to the typical cadence of litigation on serious matters such as this, and highly prejudicial to Celltrion.

Regeneron's decisions to delay suit and refuse Celltrion's offer of waiver of service created this highly compressed timeline. Yet, Regeneron's schedule fails to properly account for that compression. The Court should thus decline to enter the schedule proposed in Regeneron's Motion and, if it is inclined to enter a schedule beyond just the briefing the forthcoming motion to dismiss, enter a schedule like that proposed by Celltrion. *See Exhibit A.*

Respectfully Submitted,

CELLTRION, INC., specially appearing by counsel,

/s/ Max C. Gottlieb

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CERTIFICATE OF SERVICE

The undersigned counsel does hereby certify that on the 8th day of January, 2024, he electronically filed *Defendant Celltrion, Inc.'s Response to Plaintiff's Emergency Motion For Entry of a Schedule For Preliminary Injunction Proceedings* with the Clerk of Court using the CM/ECF system, which will send notice of same to counsel of record.

/s/ Max C. Gottlieb

Max C. Gottlieb (WVSB #13201)