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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 1:22-cv-00061-TSK

# DEFENDANT MYLAN PHARMACEUTICALS INC.'S EMERGENCY MOTION TO MODIFY SCHEDULING ORDER AND FOR EMERGENCY STATUS CONFERENCE

Defendant Mylan Pharmaceuticals Inc. ("Mylan"), by its undersigned counsel, hereby respectfully moves this Court to order Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") to immediately narrow the scope of these initial proceedings to 3 patents and 12 claims in anticipation of trial, currently set to commence in just two months, on June 12, 2023.

Despite Mylan's repeated requests, Regeneron refuses to limit the scope of this litigation commensurate with the expedited schedule it demanded. It insists on proceeding with four patents and 60 asserted claims, even though Regeneron represented to this Court that it would take no more than 12 patent claims to trial. Yet, trial is imminent. Expert discovery closes in ten days, motions for summary judgment are also due in ten days, and the Proposed Joint Pretrial Order is due in 38 days. Mylan—and the Court—should not be forced to contend with <u>five times</u> the number of patent claims during pretrial exchanges and trial, a practical impossibility under the current pretrial schedule and in the nine days the Court has allotted for trial. The time has come for Regeneron to either play its hand or cede its expedited trial schedule.

### I. BACKGROUND.

Regeneron filed this action just over eight months ago, on August 2, 2022, alleging infringement of 24 patents on the basis of Mylan's submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking approval of a biosimilar aflibercept product. (*See generally* Dkt. 1, Complaint.) Three days later, Regeneron moved the Court for an expedited status conference, seeking to "position this case for trial no later than June 2023," on a subset of patents. (Dkt. 7, Mot. Requesting Expedited Status Conf. at 1.) Even then, Regeneron acknowledged the importance of selecting "a manageable subset of the asserted patents" to litigate. (*Id.* at 6.)

Mylan challenged the feasibility of proceeding to trial in June 2023 on even a subset of the 24 asserted patents. (*See* Dkt. 26, Mylan Resp. to Mot. Requesting Expedited Status Conf. at 11-12.) On September 29, 2022, the Court held a Scheduling Conference, wherein Regeneron's counsel confirmed that it would "do further reduction with respect to the number of claims at an appropriate time," suggesting that "before trial, [Regeneron] will narrow it further." (Dkt. 90, Status Conf. Tr. at 22:16 – 23:8.) Regeneron told the Court that it was "not going to come before Your Honor asking [the Court] to adjudicate even 24 claims," "mak[ing] it manageable . . . in view of the schedule." (*Id.* at 23:8-13.) Regeneron's counsel further represented that he "would be shocked if we present more than a dozen claims to Your Honor for adjudication at trial." (*Id.* at 9:9-11.)

Because of Regeneron's representations that it would streamline the litigation in order to proceed to trial in June 2023, on October 25, 2022, the Court adopted Regeneron's proposed Scheduling Order. The parties have therefore proceeded at an unusually brisk pace, engaging in *Markman* proceedings, fact discovery, and expert report exchanges within approximately five months. (*See* Dkt. 87, Scheduling Order.) The Scheduling Order contemplated two rounds of

claim narrowing in advance of motions for summary judgment, preparation of the Proposed Joint Pretrial Order, and Trial. First, Regeneron was ordered to reduce its asserted patents to six within three days following entry of the Order.<sup>1</sup> (*Id.* at 1.) Second, the Scheduling Order (reflecting Regeneron's proposal) contemplates a further narrowing "to 3 patents and 25 claims" within "7 days after *Markman* order or 7 days after close of fact discovery, whichever is later." (*Id.* at 2.)

Accordingly, on October 28, 2022, Regeneron filed a Stipulation Regarding Claim Narrowing and Injunctive Relief, wherein it selected six patents to proceed. (*See* Dkt. 88 at 1.) Regeneron did not, at that time, select a subset of claims from those six patents for adjudication. (*Id.*) Thus, the parties' proceeded to litigate well over 100 claims through nearly three (3) months of discovery. Consequently, during *Markman* briefing, Mylan was forced to contend with well over 100 claims. (Dkt. 122, Mylan Op. Claim Construction Br. at 3-4.) Despite the ongoing prejudice to Mylan in proceeding on over 100 claims under an expedited schedule, Regeneron only hinted at further claim narrowing in its Responsive Claim Construction Brief, served December 15, 2023, where it represented to Mylan and the Court that it "[would] not present more than a dozen claims at trial." (Dkt. 174, Regeneron Resp. Claim Construction Br. at 4 n.1.)

On January 24, 2023, the Parties appeared before the Court for a *Markman* hearing to address claim construction issues on four patents and 68 claims. (*See* Dkt. 270, *Markman* Hrg. Tr. at 163:18 – 164:7.) Following the hearing, on February 10, 2023, the parties filed their respective Findings of Fact and Conclusions of Law on Claim Construction, addressing four patents and 63 patent claims. (*See* Dkt. 306, Mylan Findings of Fact and Conclusions of Law at 1, 9, 25 & 57.)

<sup>&</sup>lt;sup>1</sup> While that Scheduling Order required Regeneron to reduce the number of asserted patents to six within three days following entry of the Order, it placed no limits on the number of claims that Regeneron could assert from those six patents.

Simultaneously with the preparation of Findings of Fact and Conclusions of Law on Claim Construction, the parties began expert discovery. In its Opening Expert Reports on February 2, 2023, Regeneron continued to assert infringement of 63 patent claims, requiring hundreds of pages to address each of the elements of those asserted claims. (*See* Dkt. 287-89.) Similarly, due to the large number of claims still at issue and the distinct elements of each of those 63 patent claims, Mylan served over 1,200 pages of expert reports to adequately address invalidity issues relating to the asserted claims. (*See* Dkt. 290-96.)

On February 27, 2023, counsel for Regeneron apprised Mylan via e-mail that it "will not proceed with asserting in the first stage of the litigation claims 7 and 8 of U.S. Patent 10,888,601 and claim 15 of U.S. Patent 11,253,572." (Ex. A, 2-27-23 E. Oberwetter e-mail.) Thus, as of today, Regeneron is asserting four patents and 60 claims in this case, and as explained below, Regeneron refuses to agree to a date certain to further reduce its asserted patents and claims in advance of trial.

Faced with the completion of expert discovery, an imminent deadline for the parties to serve any motions for summary judgment and a looming deadline to submit a Proposed Joint Pretrial Order, Mylan sought some certainty that Regeneron would hold true to its representations to the Court, and also sought to establish an orderly (if expedited) schedule for efficient pretrial disclosures and preparation of the Proposed Joint Pretrial Order. Accordingly, on March 24, 2023, counsel for Mylan proposed certain dates for pretrial disclosures, predicated on Regeneron identifying, on April 14, 2023, the "3 patents and 12 claims it intends to take to trial," consistent with Regeneron's repeated representations to the Court that it "will not present more than a dozen claims at trial." (Ex. B, 3-24-23 E. Hunt e-mail; Dkt. 174, Regeneron Resp. Claim Construction Br. at 4 n.1.) One week later, on March 31, counsel for Regeneron proposed a modified schedule

for pretrial disclosures, but <u>Regeneron entirely ignored Mylan's request that it identify the patents and claims it intends to present at trial</u>. (Ex. C, 3-31-23 E. Oberwetter e-mail.) The next business day, Mylan followed-up, requesting Regeneron's prompt confirmation that it would "identify the three (3) patents and twelve (12) claims that Regeneron intends to take to trial, on April 14<sup>th</sup>, or provide a date certain on which Regeneron will make that identification." (Ex. D, 4-3-23 E. Hunt e-mail.) Thereafter, Regeneron refused to engage in further claim narrowing because "[t]he scheduling order provides the timing for further claim narrowing . . . follow[ing] the Court's order on claim construction." (Ex. E, 4-3-23 E. Oberwetter e-mail.)

# II. THE COURT SHOULD MODIFY THE SCHEDULING ORDER TO COMPEL REGENERON TO NARROW ISSUES FOR ITS EXPEDITED TRIAL.

Regeneron insists that the Court's October 25, 2022 Scheduling Order (which adopted Regeneron's proposal) justifies its delay in narrowing the initial proceedings to three patents and no more than twelve claims. (Ex. E, 4-3-23 E. Oberwetter e-mail.) But Regeneron is sitting on its hands when the parties should be working to crystallize the issues for the Court and trial. While Mylan acknowledges that this Court's Scheduling Order predicates its compulsory claim narrowing on issuance of the *Markman* order, good cause exists to modify the Scheduling Order in furtherance of the goals of Rule 16, the practicalities of pretrial exchanges and trial, and in recognition of Regeneron's own insistence that this matter must proceed in an expedited manner.

Federal Rule of Civil Procedure 16(b)(4) gives the Court broad discretion to modify its Scheduling Order upon a showing of "good cause." FED. R. CIV. P. 16(b)(4). The Local Rules of this District further provide that, among other things, "dates concerning pretrial conferences and trial[] may be modified for cause by order." L.R. CIV. P. 16.01(f)(1).

In the Fourth Circuit,

"good cause" requires "the party seeking relief [to] show that the deadlines cannot reasonably be met despite the party's diligence," and whatever other factors are

also considered, "the good-cause standard will not be satisfied if the [district] court concludes that the party seeking relief (or that party's attorney) has not acted diligently in compliance with the schedule." *See* 6A Charles Alan Wright, Arthur R. Miller, and Mary Kay Kane, Federal Practice and Procedure Civ.3d § 1522.2 (3d ed. 2010) (collecting cases)[.]

Cook v. Howard, 484 Fed. App'x 805, 815 (4th Cir. 2012); see also Harris v. Q&A Assocs., Inc., No. 2:16-CV-46, 2018 WL 8458206, at \*1-\*2 (N.D.W. Va. June 20, 2018); see also Selders v. Megacorp Logistics, LLC, No. 2:14-cv-60, 2015 WL 12910711, at \*2 (N.D.W. Va. Apr. 28, 2015). Moreover, Rule 16 mandates that a court issue a Scheduling Order in furtherance of certain specific goals, including "expediting disposition of the action" and "discouraging wasteful pretrial activities." FED. R. CIV. P. 16(a); see also FED. R. CIV. P. 16(b)(1). Evaluating these goals in view of this case's procedural posture establishes that good cause exists to modify the Scheduling Order.

Expediting Disposition of the Action. It is only because of Regeneron's insistence on expediting this litigation that the current Scheduling Order is unworkable. In a typical case, the parties would have ample time to narrow issues for trial through dispositive motions and pretrial exchanges. Yet this case is anything but typical. Ironically, Regeneron now refuses to narrow the issues for trial, when it was adamant just months ago that it would do whatever necessary to ensure the case proceeded to trial in June 2023. To the extent that the trial date will hold, and Regeneron continues to insist on expedited disposition of the initial phase of this matter, good cause exists to modify the Scheduling Order in furtherance of that goal.

**Discouraging Wasteful Pretrial Activities**. At present, Regeneron is proposing that the parties engage in dispositive motion practice and preparation of the Proposed Joint Pretrial Order on <u>five times</u> more patent claims than it intends to have tried. Further, Regeneron is also required under the current Scheduling Order to drop one of the patents it is currently asserting, which could result in substantial narrowing of the issues for trial, particularly to the extent that Regeneron drops

either the 865 formulation patent or the 715 manufacturing patent.<sup>2</sup> Modifying the Scheduling Order to compel Regeneron to immediately narrow the scope of these initial proceedings to the no more than three (3) patents and twelve (12) claims it already promised, (Dkt. 174, Regeneron Resp. Claim Construction Br. at 4 n.1), is necessary to avoid wasteful pretrial activities, causes no prejudice to Regeneron, and is indeed required if this case is to proceed to trial in June.

First, engaging in further pretrial activities before claim narrowing would only waste the Court's and the parties' resources. To the extent that the parties file motions for summary judgment—currently due just ten days from today—any such motions will necessarily address claims that Regeneron does not intend to take to trial. Forcing the parties to prepare dispositive motions on claims that will ultimately be dropped is an exercise in futility and clearly a wasteful use of the Court's and parties' resources.

Second, if trial is to proceed in June, the parties must prepare the Proposed Joint Pretrial Order in the next five weeks, addressing the requirements of Local Rule 16.04(b) for each asserted patent claim, resulting in a pretrial order many times more voluminous than necessary or contemplated under the current Scheduling Order. Recognizing this, Mylan proposed that Regeneron agree to narrow the issues in advance of pretrial exchanges, (Ex. B, 3-24-23 E. Hunt e-mail), but Regeneron insists on engaging in wasteful pretrial activities through the preparation of a pretrial order addressing at least 48 patent claims—and likely hundreds of claim elements—that Regeneron admits will not proceed to trial (Ex. E, 4-3-23 E. Oberwetter e-mail). As Regeneron demanded this expedited schedule, it should bear the burden of reducing the claims to a

<sup>&</sup>lt;sup>2</sup> At present, the parties are relying on the opinions of fourteen (14) expert witnesses to support their claims and defenses with respect to the patents and claims currently at issue. If Regeneron were to drop either the 865 formulation patent or the 715 manufacturing patent, a minimum of three (3) expert witnesses would no longer testify at the trial because an entire technology area would no longer be at issue.

manageable amount—as it told the Court it would—and it should do so before motions for summary judgment and preparation of the Joint Proposed Pretrial Order.

Third, Regeneron simply cannot reasonably take 60 claims to trial. It has repeatedly told this Court that it will not present more than a dozen claims, and even if Regeneron were to move forward with its unreasonable 60 claims, it is practically impossible for the parties and the Court to litigate those claims within the nine (9) days that the Court has allotted for trial.

Through this emergency motion, Mylan does not seek to delay. To the contrary, Mylan has established that good cause exists to alleviate any further delay in preparing this matter for trial. Regeneron is the party injecting delay, and absent the relief requested by Mylan, there is a real risk that Scheduling Order deadlines cannot be met.

Mylan Has Acted Diligently. Mylan made significant efforts to comply with the Scheduling Order, including producing over one million pages of documents, conducting over 20 depositions during fact discovery, and serving over 1,200 pages of expert reports addressing the invalidity of the claims at issue alone, all while repeatedly requesting that Regeneron reduce issues for trial. Most recently, Mylan proposed that Regeneron identify its selected three patents and 12 claims by April 14, 2023, which Mylan views as imperative if this matter will proceed to trial in June. (Ex. B, 3-24-23 E. Hunt e-mail.) Throughout, Regeneron has refused to limit the subject matter at issue consistent with the schedule it demanded.

**Regeneron Will Not Be Prejudiced.** Regeneron chose to put this litigation on the fast track, yet Regeneron is riding the brakes on the eve of trial to gain a strategic advantage and prejudice Mylan. Mylan's requested modification is not seeking to impart delay. To the contrary, Mylan seeks to *expedite* the crystallization of issues for an imminent trial.

Should Regeneron assert that it would be prejudiced by Mylan's requested modification, ostensibly because it requires the Court to construe certain disputed terms found within the patent claims currently at issue, Regeneron must then choose whether it wishes to maintain the expedited schedule it imposed, or potentially forego an early trial in favor of strategic certainty. Months ago, during the *Markman* hearing, Regeneron already had in mind the claims it was likely to take to trial, and it now has the benefit of full expert discovery on over 60 patent claims—more than enough to permit Regeneron to select patents and claims for trial, regardless of any outstanding claim construction issues.

Regeneron alone is in control of the flow of traffic here: either it selects the three patents and 12 claims it wishes to try in this litigation, or the race to the finish slows, and the parties proceed to trial at some future point. Regeneron must select its line, and it must do so now.

\* \* \*

For at least the above reasons, good cause exists to modify the Scheduling Order and to compel Regeneron to narrow the scope of the litigation to three patents and 12 claims prior to the filing of summary judgment motions and pretrial exchanges, in anticipation of a June trial.

# III. AN EMERGENCY STATUS CONFERENCE IS NECESSARY TO ASSESS THE FEASIBILITY OF PROCEEDING TO TRIAL ON JUNE 12TH.

As Mylan's emergency motion to modify the Scheduling Order makes clear, Regeneron's refusal to limit the scope of this case in advance of trial calls into question the feasibility of proceeding to trial on June 12, 2023. Absent the narrowing of issues that the Scheduling Order contemplated would occur months ago, Mylan believes that the parties will be unable to submit a Proposed Joint Pretrial Order on May 18, 2023 and, perhaps most importantly, the parties and the Court will be forced to contend with <u>five times</u> the number of patent claims—totaling hundreds of additional claim elements—which the parties must address in their proofs both prior to trial and

during trial. Simply put, assuming Regeneron's continued refusal to meaningfully limit the case, it is a practical impossibility to maintain the current pretrial and trial schedule.

## IV. CONCLUSION

For the reasons set forth herein, Mylan respectfully requests that the Court grant Mylan's emergency motion to modify the Scheduling Order and convene an emergency status conference to discuss preparations for trial, currently set for June 12, 2023.

Dated: April 10, 2023

*Of Counsel (admitted pro hac vice):* Of Counsel (admitted pro hac vice): William A. Rakoczy Deanne M. Mazzochi Heinz J. Salmen Eric R. Hunt Jeff A. Marx Neil B. McLaughlin Lauren M. Lesko L. Scott Beall Thomas H. Ehrich Steven J. Birkos Katie A. Boda Abraham J. Varon Jake R. Ritthamel RAKOCZY MOLINO MAZZOCHI SIWIK LLP 6 W. Hubbard St., Suite 500 Chicago, IL 60654 (312) 527-2157 wrakoczy@rmmslegal.com dmazzochi@rmmslegal.com hsalmen@rmmslegal.com ehunt@rmmslegal.com jmarx@rmmslegal.com nmclaughlin@rmmslegal.com llesko@rmmslegal.com sbeall@rmmslegal.com tehrich@rmmslegal.com sbirkos@rmmslegal.com kboda@rmmslegal.com avaron@rmmslegal.com

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STEPTOE & JOHNSON PLLC

## /s/ William J. O'Brien

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Attorneys for Defendant Mylan Pharmaceuticals Inc.

### **CERTIFICATE OF SERVICE**

I certify that on the 10th day of April 2023, I filed the foregoing "DEFENDANT MYLAN PHARMACEUTICALS INC.'S EMERGENCY MOTION TO MODIFY SCHEDULING ORDER AND FOR EMERGENCY STATUS CONFERENCE" using the Court's CM/ECF system, which will send notification of the filing to all counsel of record.

### /s/ William J. O'Brien

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Attorneys for Defendant Mylan Pharmaceuticals Inc.

# Exhibit A

to Mylan Emergency Motion to Modify Scheduling Order and for Emergency Status Conference

# Case 1:22-cv-00061-TSK-JPM Document 415-1 Filed 04/10/23 Page 2 of 2 PageID #:

From: Oberwetter, Ellen

M710 Team; Gordon Copland; Jamie O"Brien To:

Eylea; REGENERON PATENT; Steve Ruby; David Pogue Cc:

Subject: Regeneron v. Mylan - claim narrowing Date: Monday, February 27, 2023 16:38:53

#### Counsel,

As part of Regeneron's continued good-faith effort to narrow the scope of the case, Regeneron will not proceed with asserting in the first stage of the litigation claims 7 and 8 of U.S. Patent 10,888,601 and claim 15 of U.S. Patent 11,253,572.

Please also note that although it should be obvious from the overall content of Dr. Csaky's report, there is a typo at paragraph 319 that inadvertently omitted claim 12 of the '601 patent from the list of those still being asserted, which it is. Claim 12 was included in the table of contents and is discussed substantively in the report.

Thanks, Ellen

## Ellen E. Oberwetter Williams & Connolly LLP

680 Maine Ave., S.W., Washington, DC 20024 (Cell) 703-628-3595 | (Office) 202-434-5849 eoberwetter@wc.com | www.wc.com/eoberwetter

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# Exhibit B

to Mylan Emergency Motion to Modify Scheduling Order and for Emergency Status Conference

# Case 1:22-cv-00061-TSK-JPM Document 415-2 Filed 04/10/23 Page 2 of 3 PageID #: 24104

From: Eric R. Hunt

To: <u>Eylea</u>; <u>REGENERON PATENT</u>; <u>Steve Ruby</u>; <u>"David Pogue"</u>

Cc: M710 Team; Gordon Copland; Jamie O"Brien

Subject: Regeneron v. Mylan - Pretrial Disclosures

Date: Friday, March 24, 2023 16:20:19

#### Counsel,

The Court's Scheduling Order contemplates filing of a Proposed Joint Pretrial Order and Joint Stipulation of Facts on May 18, 2023. In order to ensure an orderly, cooperative and constructive exchange of information in the course of compiling these required pretrial documents, Mylan wishes to establish a schedule for exchanges of drafts of these documents to facilitate a timely filing on May 18<sup>th</sup>. Specifically, Mylan suggests that the parties approach the Final Pretrial Order and Joint Stipulation of Facts in a similar matter as routinely done in the District of Delaware, which we understand is relatively common in this district. Additionally, Mylan would like to put in place a procedure to streamline motions *in limine* (if any) by agreeing that opening and response briefing on each motion *in limine* shall be limited to three pages of argument.

Accordingly, Mylan proposes the following deadlines:

- 1. **April 14, 2023**: Regeneron to provide:
  - a. identification of the 3 patents and 12 claims it intends to take to trial (Dkt. 174, Responsive Claim Construction Br. at 4 n.1); and
  - b. draft Proposed Joint Pretrial Order and Joint Stipulation of Facts, including proposed language for the sections to be jointly submitted by the parties, as well as sections related to Regeneron's case;
- 2. **April 25, 2023**: Parties to simultaneously exchange deposition designations pursuant to Fed. R. Civ. P. 26(a)(3)(A)(ii).
- 3. **April 28, 2023**:
  - a. Mylan to provide responses to Regeneron's draft Proposed Joint Pretrial Order and Joint Stipulation of Facts, as well as sections related to Mylan's case; and
  - b. Parties to simultaneously exchange exhibit lists, as well as a copy of proposed trial exhibits.
- 4. **May 5, 2023:** Parties to simultaneously exchange objections to initial deposition designations and any counter-designations.
- 5. May 12, 2023: Parties to simultaneously exchange
  - a. objections to proposed trial exhibits; and
  - b. objections to any deposition counter-designations.
- 6. **May 15, 2023:** Parties to commence meet and confer efforts to identify and resolve disputes in an effort to finalize Joint Final Pretrial Order and Joint Stipulation of Facts.

Please confirm Regeneron's agreement to the above proposal no later than March 29<sup>th</sup>. We are available to discuss.

### ERIC R. HUNT | PARTNER

EHUNT@RMMSLEGAL.COM DIRECT | 312.222.6314 OFFICE | 312.527.2157



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This email message and any attachments are being sent by Rakoczy Molino Mazzochi Siwik LLP, are confidential, and may be privileged. If you are not the intended recipient, please notify us immediately by replying to this message, and destroy all copies of this message and any attachments. Thank you.

# Exhibit C

to Mylan Emergency Motion to Modify Scheduling Order and for Emergency Status Conference

# Case 1:22-cv-00061-TSK-JPM Document 415-3 Filed 04/10/23 Page 2 of 5 PageID #: 24107

From: Oberwetter, Ellen

To: <u>Eric R. Hunt; Eylea; REGENERON PATENT; Steve Ruby; "David Pogue"</u>

Cc: M710 Team; Gordon Copland; Jamie O"Brien

Subject: RE: Regeneron v. Mylan - Pretrial Disclosures

**Date:** Friday, March 31, 2023 14:39:36

Eric, I am getting back to you on Mylan's proposed schedule. We propose the following modifications, and please let me know if you'd like to discuss.

Thanks, Ellen

### 1. April 14, 2023 (Friday):

- a. Regeneron to provide:
  - 1. Draft Proposed Joint Pretrial Order shell and Joint Stipulation of Facts, including proposed language for the sections to be jointly submitted by the parties

#### 2. April 21, 2023 (Friday):

- a. Parties simultaneously exchange
  - 1. Contested FOF/COL (10 pages max each) on issues for which they bear the burden
  - 2. "Essential elements" on issues for which they bear the burden
- b. Mylan to provide edits to pretrial order shell and joint stipulation of facts

### 3. April 28, 2023 (Friday):

- a. Parties to simultaneously exchange:
  - 1. Deposition designations pursuant to Fed. R. Civ. P. 26(a)(3)(A)(ii).
  - 2. Witness lists
  - 3. Exhibit lists
- a. Regeneron to circulate revised pretrial order shell and joint stipulation of facts

### 4. May 5, 2023 (Friday):

a. Parties exchange electronic copies of exhibits on exhibit list

#### 5. May 12, 2023 (Friday):

- a. Parties to simultaneously exchange:
  - 1. Objections to initial deposition designations and any counter-designation
  - 2. Responsive contested FOF/COL and "essential elements" (on issues on which party does not bear burden) (again, 10 pages max each)
  - 3. Objections to proposed trial exhibits; and
  - 4. Brief summary of material facts and theories of liability (15 pages max)

#### 6. May 15, 2023 (Monday):

- a. Parties to exchange objections to any deposition counter designations
- b. Parties to commence meet and confer efforts to identify and resolve disputes in an effort to finalize Joint Final Pretrial Order and Joint Stipulation of Facts.

Ellen E. Oberwetter Williams & Connolly LLP

680 Maine Ave SW | Washington, DC 20024 (Cell) 703-628-3595 | (Office) 202-434-5849 eoberwetter@wc.com | www.wc.com/eoberwetter

From: Oberwetter, Ellen <EOberwetter@wc.com>

**Sent:** Tuesday, March 28, 2023 4:06 PM

**To:** Eric R. Hunt <ehunt@rmmslegal.com>; Eylea <Eylea@wc.com>; REGENERON PATENT <REGENERONPATENT@lists.kellogghansen.com>; Steve Ruby <sruby@cdkrlaw.com>; 'David Pogue' <drpogue@cdkrlaw.com>

**Cc:** M710 Team < M710 Team@rmmslegal.com>; Gordon Copland < Gordon.Copland@Steptoe-Johnson.com>; Jamie O'Brien < Jamie.Obrien@Steptoe-Johnson.com>

Subject: RE: Regeneron v. Mylan - Pretrial Disclosures

Eric, thanks for sending the below. We agree it makes sense to come up with dates that will facilitate the Joint Pretrial Order and Stipulation of Facts. We are considering the dates and processes you propose below and will get back to you on them this week, although it may not be tomorrow.

Thanks, Ellen

## Ellen E. Oberwetter Williams & Connolly LLP

680 Maine Ave SW | Washington, DC 20024 (Cell) 703-628-3595 | (Office) 202-434-5849 eoberwetter@wc.com | www.wc.com/eoberwetter

**From:** Eric R. Hunt < <a href="mailto:ehunt@rmmslegal.com">ehunt@rmmslegal.com</a>>

**Sent:** Friday, March 24, 2023 5:20 PM

To: Eylea <<u>Eylea@wc.com</u>>; REGENERON PATENT <<u>REGENERONPATENT@lists.kellogghansen.com</u>>;

Steve Ruby <<u>sruby@cdkrlaw.com</u>>; 'David Pogue' <<u>drpogue@cdkrlaw.com</u>>

 $\textbf{Cc:} \ \mathsf{M710\,Team} < \underline{\mathsf{M710Team@rmmslegal.com}} >; \ \mathsf{Gordon\,Copland} < \underline{\mathsf{Gordon.Copland@Steptoe-}}$ 

<u>Johnson.com</u>>; Jamie O'Brien <<u>Jamie.Obrien@Steptoe-Johnson.com</u>>

**Subject:** Regeneron v. Mylan - Pretrial Disclosures

Counsel,

The Court's Scheduling Order contemplates filing of a Proposed Joint Pretrial Order and Joint Stipulation of Facts on May 18, 2023. In order to ensure an orderly, cooperative and constructive exchange of information in the course of compiling these required pretrial documents, Mylan wishes to establish a schedule for exchanges of drafts of these documents to facilitate a timely filing on May 18<sup>th</sup>. Specifically, Mylan suggests that the parties approach the Final Pretrial Order and Joint Stipulation of Facts in a similar matter as routinely done in the District of Delaware, which we understand is relatively common in this district. Additionally, Mylan would like to put in place a procedure to streamline motions *in limine* (if any) by agreeing that opening and response briefing on each motion *in limine* shall be limited to three pages of argument.

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Please confirm Regeneron's agreement to the above proposal no later than March 29<sup>th</sup>. We are available to discuss.

- Eric

#### ERIC R. HUNT | PARTNER

EHUNT@RMMSLEGAL.COM

DIRECT | 312.222.6314 OFFICE | 312.527.2157



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# Case 1:22-cv-00061-TSK-JPM Document 415-3 Filed 04/10/23 Page 5 of 5 PageID #: 24110

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# Exhibit D

to Mylan Emergency Motion to Modify Scheduling Order and for Emergency Status Conference

# Case 1:22-cv-00061-TSK-JPM Document 415-4 Filed 04/10/23 Page 2 of 6 PageID #: 24112

From: Eric R. Hunt

To: Oberwetter, Ellen; Eylea; REGENERON PATENT; Steve Ruby; "David Pogue"

Cc: M710 Team; Gordon Copland; Jamie O"Brien
Subject: RE: Regeneron v. Mylan - Pretrial Disclosures

**Date:** Monday, April 3, 2023 08:17:01

Ellen,

We are evaluating Regeneron's response to Mylan's proposal regarding pretrial disclosures, and there is a pressing issue that requires attention. Regeneron has, once again, refused to address Mylan's request that Regeneron identify the patents and claims that Regeneron intends to take to trial. Surprisingly, your e-mail completely ignores Mylan's proposal that Regeneron identify the three (3) patents and twelve (12) claims that Regeneron intends to take to trial, on April 14<sup>th</sup>.

While Mylan continues to believe that Regeneron should have limited the scope of this case prior to expert discovery, it is imperative that Regeneron narrow the case in advance of the dispositive motion deadline and preparation of the pretrial order. Mylan cannot agree to waste time and resources on potentially futile issues in connection with dispositive motion and pretrial activities, which is why Mylan's schedule is premised on Regeneron narrowing the scope of the case prior to commencement of those activities.

By end of day tomorrow, please either accept Mylan's proposal to identify the three (3) patents and twelve (12) claims that Regeneron intends to take to trial, on April 14<sup>th</sup>, or provide a date certain on which Regeneron will make that identification, so that we can meaningfully assess the feasibility of proceeding with dispositive motions and pretrial activities.

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# Case 1:22-cv-00061-TSK-JPM Document 415-4 Filed 04/10/23 Page 3 of 6 PageID #: 24113

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From: Oberwetter, Ellen <EOberwetter@wc.com>

**Sent:** Friday, March 31, 2023 14:39

**To:** Eric R. Hunt <ehunt@rmmslegal.com>; Eylea <Eylea@wc.com>; REGENERON PATENT <REGENERONPATENT@lists.kellogghansen.com>; Steve Ruby <sruby@cdkrlaw.com>; 'David Pogue' <drpogue@cdkrlaw.com>

**Cc:** M710 Team < M710 Team@rmmslegal.com>; Gordon Copland < Gordon.Copland@Steptoe-Johnson.com>; Jamie O'Brien < Jamie.Obrien@Steptoe-Johnson.com>

**Subject:** RE: Regeneron v. Mylan - Pretrial Disclosures

Eric, I am getting back to you on Mylan's proposed schedule. We propose the following modifications, and please let me know if you'd like to discuss.

Thanks, Ellen

### 1. April 14, 2023 (Friday):

- a. Regeneron to provide:
  - 1. Draft Proposed Joint Pretrial Order shell and Joint Stipulation of Facts, including proposed language for the sections to be jointly submitted by the parties

### 2. April 21, 2023 (Friday):

- a. Parties simultaneously exchange
  - 1. Contested FOF/COL (10 pages max each) on issues for which they bear the burden
  - 2. "Essential elements" on issues for which they bear the burden
- b. Mylan to provide edits to pretrial order shell and joint stipulation of facts

### 3. April 28, 2023 (Friday):

- a. Parties to simultaneously exchange:
  - 1. Deposition designations pursuant to Fed. R. Civ. P. 26(a)(3)(A)(ii).
  - 2. Witness lists
  - 3. Exhibit lists
- a. Regeneron to circulate revised pretrial order shell and joint stipulation of facts

#### 4. May 5, 2023 (Friday):

a. Parties exchange electronic copies of exhibits on exhibit list

### 5. May 12, 2023 (Friday):

- a. Parties to simultaneously exchange:
  - 1. Objections to initial deposition designations and any counter-designation
  - 2. Responsive contested FOF/COL and "essential elements" (on issues on which party does not bear burden) (again, 10 pages max each)
  - 3. Objections to proposed trial exhibits; and
  - 4. Brief summary of material facts and theories of liability (15 pages max)

### 6. May 15, 2023 (Monday):

a. Parties to exchange objections to any deposition counter designations

b. Parties to commence meet and confer efforts to identify and resolve disputes in an effort to finalize Joint Final Pretrial Order and Joint Stipulation of Facts.

# Ellen E. Oberwetter Williams & Connolly LLP

680 Maine Ave SW | Washington, DC 20024 (Cell) 703-628-3595 | (Office) 202-434-5849 eoberwetter@wc.com | www.wc.com/eoberwetter

**From:** Oberwetter, Ellen < <u>EOberwetter@wc.com</u>>

**Sent:** Tuesday, March 28, 2023 4:06 PM

**To:** Eric R. Hunt <<u>ehunt@rmmslegal.com</u>>; Eylea <<u>Eylea@wc.com</u>>; REGENERON PATENT <<u>REGENERONPATENT@lists.kellogghansen.com</u>>; Steve Ruby <<u>sruby@cdkrlaw.com</u>>; 'David Pogue' <<u>drpogue@cdkrlaw.com</u>>

**Cc:** M710 Team < M710Team@rmmslegal.com >; Gordon Copland < Gordon.Copland@Steptoe-Johnson.com >; Jamie O'Brien < Jamie.Obrien@Steptoe-Johnson.com >

**Subject:** RE: Regeneron v. Mylan - Pretrial Disclosures

Eric, thanks for sending the below. We agree it makes sense to come up with dates that will facilitate the Joint Pretrial Order and Stipulation of Facts. We are considering the dates and processes you propose below and will get back to you on them this week, although it may not be tomorrow.

Thanks, Ellen

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680 Maine Ave SW | Washington, DC 20024 (Cell) 703-628-3595 | (Office) 202-434-5849 eoberwetter@wc.com | www.wc.com/eoberwetter

**From:** Eric R. Hunt < <a href="mailto:ehunt@rmmslegal.com">ehunt@rmmslegal.com</a>>

**Sent:** Friday, March 24, 2023 5:20 PM

**To:** Eylea <<u>Eylea@wc.com</u>>; REGENERON PATENT <<u>REGENERONPATENT@lists.kellogghansen.com</u>>;

Steve Ruby <<u>sruby@cdkrlaw.com</u>>; 'David Pogue' <<u>drpogue@cdkrlaw.com</u>>

Cc: M710 Team < M710Team@rmmslegal.com >; Gordon Copland < Gordon.Copland@Steptoe-

<u>Johnson.com</u>>; Jamie O'Brien <<u>Jamie.Obrien@Steptoe-Johnson.com</u>>

**Subject:** Regeneron v. Mylan - Pretrial Disclosures

Counsel,

The Court's Scheduling Order contemplates filing of a Proposed Joint Pretrial Order and Joint Stipulation of Facts on May 18, 2023. In order to ensure an orderly, cooperative and constructive

exchange of information in the course of compiling these required pretrial documents, Mylan wishes to establish a schedule for exchanges of drafts of these documents to facilitate a timely filing on May 18<sup>th</sup>. Specifically, Mylan suggests that the parties approach the Final Pretrial Order and Joint Stipulation of Facts in a similar matter as routinely done in the District of Delaware, which we understand is relatively common in this district. Additionally, Mylan would like to put in place a procedure to streamline motions *in limine* (if any) by agreeing that opening and response briefing on each motion *in limine* shall be limited to three pages of argument.

Accordingly, Mylan proposes the following deadlines:

- 1. **April 14, 2023**: Regeneron to provide:
  - a. identification of the 3 patents and 12 claims it intends to take to trial (Dkt. 174, Responsive Claim Construction Br. at 4 n.1); and
  - b. draft Proposed Joint Pretrial Order and Joint Stipulation of Facts, including proposed language for the sections to be jointly submitted by the parties, as well as sections related to Regeneron's case;
- 2. **April 25, 2023**: Parties to simultaneously exchange deposition designations pursuant to Fed. R. Civ. P. 26(a)(3)(A)(ii).
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  - a. Mylan to provide responses to Regeneron's draft Proposed Joint Pretrial Order and Joint Stipulation of Facts, as well as sections related to Mylan's case; and
  - b. Parties to simultaneously exchange exhibit lists, as well as a copy of proposed trial exhibits.
- 4. **May 5, 2023:** Parties to simultaneously exchange objections to initial deposition designations and any counter-designations.
- 5. May 12, 2023: Parties to simultaneously exchange
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Please confirm Regeneron's agreement to the above proposal no later than March 29<sup>th</sup>. We are available to discuss.

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# Exhibit E

to Mylan Emergency Motion to Modify Scheduling Order and for Emergency Status Conference

# Case 1:22-cv-00061-TSK-JPM Document 415-5 Filed 04/10/23 Page 2 of 6 PageID #: 24118

From: Oberwetter, Ellen

To: <u>Eric R. Hunt; Eylea; REGENERON PATENT; Steve Ruby; "David Pogue"</u>

Cc: M710 Team; Gordon Copland; Jamie O"Brien

Subject: RE: Regeneron v. Mylan - Pretrial Disclosures

**Date:** Monday, April 3, 2023 11:33:10

Eric,

We did not address claim narrowing because it is covered by the existing scheduling order. No one is wasting Mylan's resources. The scheduling order provides the timing for further claim narrowing which quite logically will follow the Court's order on claim construction. Please let us know if you'd like to discuss further.

Thanks, Ellen

# Ellen E. Oberwetter Williams & Connolly LLP

680 Maine Ave SW | Washington, DC 20024 (Cell) 703-628-3595 | (Office) 202-434-5849 eoberwetter@wc.com | www.wc.com/eoberwetter

From: Eric R. Hunt <ehunt@rmmslegal.com>

**Sent:** Monday, April 3, 2023 9:17 AM

**To:** Oberwetter, Ellen <EOberwetter@wc.com>; Eylea <Eylea@wc.com>; REGENERON PATENT <REGENERONPATENT@lists.kellogghansen.com>; Steve Ruby <sruby@cdkrlaw.com>; 'David Pogue' <drpogue@cdkrlaw.com>

**Cc:** M710 Team < M710 Team@rmmslegal.com>; Gordon Copland < Gordon.Copland@Steptoe-Johnson.com>; Jamie O'Brien < Jamie.Obrien@Steptoe-Johnson.com>

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