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 five times 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.

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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

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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.[1] (*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.)

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[1] 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.

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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

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for pretrial disclosures, but Regeneron entirely ignored Mylan's request that it identify the patents and claims it intends to present at trial. (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 14th, 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

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