

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Case No. 1:22-cv-00061-TSK

JURY TRIAL DEMANDED

**REGENERON’S RESPONSE TO MYLAN’S EMERGENCY MOTION TO
MODIFY SCHEDULING ORDER AND FOR EMERGENCY STATUS CONFERENCE**

Yet again Mylan seeks to alter this Court’s Scheduling Order. Although it does not ask to disturb the trial date in June, Mylan wishes to impose on Regeneron a new claim-narrowing requirement that contravenes this Court’s Scheduling Order without any commensurate narrowing of Mylan’s voluminous defenses. Regeneron wholeheartedly agrees that “the parties should be working to crystallize the issues for the Court and trial.” ECF 415 (“Mot.”) at 5. What Mylan seeks, however, is not cooperative narrowing but Regeneron’s unilateral disarmament. If the Court is inclined to impose additional case-narrowing events beyond those currently specified in the Scheduling Order, it should reject Mylan’s proposal and instead require mutual narrowing as detailed below.

Regeneron already has narrowed its case significantly—and has done so above and beyond the requirements of the Scheduling Order. First, consistent with the Court’s Scheduling Order, Regeneron selected six of its 24 asserted patents for trial in June. Then, to streamline the case further, Regeneron *voluntarily* narrowed to only four patents and 60 total claims. Mylan’s motion glosses over these unilateral claim-narrowing efforts by Regeneron. Mylan also

downplays the next operative claim-narrowing requirement specified in the Court’s Scheduling Order—namely, a narrowing to 3 patents and 25 claims within 7 days after this Court’s *Markman* order. In addition to that forthcoming narrowing event, Regeneron has also committed to further narrow for trial to only a dozen claims in total. In short, this case has already been substantially narrowed, and it will be narrowed further still in the run-up to trial.

Whereas Regeneron has scrupulously adhered to every deadline set forth in the Court’s Scheduling Order, including its claim narrowing obligations, Mylan has flouted the Scheduling Order at nearly every turn. Indeed, Mylan served no fewer than *three late reports* from *three different experts* after the deadlines specified in this Court’s Scheduling Order, without seeking leave of Court or proffering any excuse for doing so. It is astounding, therefore, that Mylan now approaches the Court—without first conferring with Regeneron—to complain about a supposed failure to comply with a requirement that Mylan created only by ignoring the clear claim-narrowing requirements of the Scheduling Order. Nothing supports Mylan’s argument that “[t]he time has come for Regeneron” to narrow its case (Mot. 1). The time for further case narrowing is specified by the Scheduling Order—not by Mylan’s say-so.

Even more brazenly, Mylan asks the Court to compel Regeneron to further narrow its case now, in advance of the Scheduling Order’s deadline, without any commensurate reduction in Mylan’s litany of asserted prior art references. That is contrary to both precedent and basic fairness: mandatory claim reduction should not “deny the patentee ‘the opportunity to determine whether particular claims might raise separate issues of infringement or invalidity in light of the defendants’ accused products and proposed defenses.’” *Allergan, Inc. v. Teva Pharm. USA*, 2017 WL 373462, at *2 (E.D. Tex. Jan. 26, 2017) (quoting *In re Katz*, 639 F.3d 1303, 1309 (Fed. Cir. 2011)).

Mylan has no actual basis for concern over the case schedule or the timing of further claim narrowing events. The upcoming narrowing deadline in the Court's Scheduling Order is simply a reflection of the practical reality that deciding which claims to assert at trial will depend on the Court's resolution of the parties' disputes over the meaning of the claims. Regeneron, of course, will further narrow its case within seven days of the issuance of the Court's *Markman* ruling, as specified in the Scheduling Order. In every respect, the case is fully on track: expert discovery is proceeding on schedule, with expert depositions fully scheduled and now underway; and preparation of the joint pretrial order has begun. Mylan's stated concern that "Regeneron simply cannot reasonably take 60 claims to trial" is a red herring; Regeneron will abide by its prior representations to the Court that it will not present more than a dozen claims at trial. Mylan's rhetoric aside, the case is currently manageable and will remain so up to and through trial in June.

In addition, as part of its ongoing endeavor to streamline this case for trial, Regeneron is amenable to accommodating Mylan's request for an additional narrowing event now, but only if Mylan commensurately narrows its bloated patchwork of defenses. *See id.* at *3 ("[T]he venerable legal principle that 'what is sauce for the goose is sauce for the gander' applies here." (quoting *Heffernan v. City of Paterson*, 578 U.S. 266, 272 (2016))). Under this compromise proposal, Regeneron would narrow to 40 claims by April 27, followed one week later (May 4) by Mylan narrowing to no more than six total asserted prior-art references, double-patenting references, or defenses under 35 U.S.C. § 112 per patent. Regeneron will then further narrow its case to 3 patents and 25 claims by the deadline currently specified in the Scheduling Order, and will not present more than 12 claims at trial. The Court should thus reject Mylan's latest attempt to unilaterally disregard the deadlines specified in this Court's Scheduling Order.

I. Background

The Scheduling Order entered at the start of this case set forth two points at which Regeneron must narrow claims. The first has already occurred: consistent with the Scheduling Order, last fall Regeneron narrowed from the 24 patents in its Complaint to 6 patents from 3 patent families. ECF 87 (Scheduling Order) at 1; ECF 88 (Oct. 28, 2022 Stipulation Regarding Case Narrowing and Injunctive Relief). The second deadline has not yet occurred. Seven days after the later of the *Markman* order or the close of fact discovery, Regeneron must narrow to 3 patents and 25 claims. ECF 87 at 2. While Mylan accuses Regeneron of “sitting on its hands,” Mylan does not (and cannot) dispute that Regeneron has complied scrupulously with the Scheduling Order. In fact, Regeneron has narrowed beyond what was contemplated in the Scheduling Order, by voluntarily narrowing the patents and claims at issue to 60 claims from 4 patents. Mot. 3-4.

Mylan, on the other hand, has repeatedly violated the Scheduling Order’s expert discovery deadlines and has presented a thicket of dubious defenses that it cannot reasonably present at trial. Mylan has served three untimely expert reports. First, although Mylan’s opening expert reports were due February 2, ECF 87 at 2, Mylan, without notice or agreement, served an untimely report a week later, on February 9, 2023. ECF 304. Second, Mylan served another expert report one month out of time on March 2, purporting to unveil a “prior commercial use” defense. Mylan agreed to withdraw this defense, ECF 362, only after Regeneron prepared and filed a motion to exclude it as waived and untimely, ECF 342-2. Third, on March 30, Mylan served a responsive report four weeks late, disclosing a noninfringement defense that should have been disclosed on March 2. ECF 400.

As to the content of Mylan’s reports, it is anyone’s guess what defenses Mylan actually

intends to present at trial. Mylan so far has served 19 expert reports from 9 different witnesses, nearly twice Regeneron's 11 reports from 5 experts. Mylan has also cited to well over 100 prior art references against Regeneron's four patents from three patent families. One of Mylan's proffered experts on the '865 patent, Dr. Rabinow, cites to 46 prior art references in his report; Dr. Albin, addressing the '572 and '601 method of treatment patents, cites to 119 supposed prior art references. Despite Mylan's repeated requests for Regeneron to narrow its claims, Mylan has never proposed mutual narrowing of claims and defenses. When Regeneron declined Mylan's request for further, unilateral claim narrowing beyond that contemplated in the Scheduling Order, Mot. 4-5, Mylan declined to meet and confer with Regeneron and instead filed the instant motion.

II. Argument

Regeneron is committed to maintaining the present trial date, and Mylan's motion does not request a delay in that respect. The case is continuing on track, with expert discovery currently in progress. Regeneron is likewise committed to complying with the Scheduling Order's existing claim-narrowing deadline—namely, a narrowing to three patents and 25 claims within 7 days of the issuance of this Court's *Markman* order. And Regeneron is committed to proceeding to trial with only 12 claims in total, as it has represented to the Court on two other occasions. ECF 90 at 9:9-11; ECF 174-2 at 4 n.1.

Nonetheless, as a reasonable compromise in response to Mylan's desire for a further claim-narrowing event, Regeneron is amenable to narrowing to four patents and 40 claims by April 27, provided that one week later (May 4) Mylan narrows to no more than six total asserted prior-art references, double-patenting references, or defenses under 35 U.S.C. § 112 per patent. Such staged, mutual narrowing is typical in patent cases and rightly places the burden of

streamlining the case on both parties. *See Allergan*, 2017 WL 373462, at *2-3; *Certusview Techs., LLC v. S & N Locating Services, LLC*, 2014 WL 4930803, at *7 (E.D. Va. Oct. 1, 2014) (ordering defendant to limit number of asserted prior art references alongside plaintiff's claim narrowing); *SynQor, Inc. v. Artesyn Techs., Inc.*, 2011 WL 3625036, at *18 (E.D. Tex. Aug. 17, 2011), *aff'd*, 709 F.3d 1365 (Fed. Cir. 2013) ("If the [] Defendants believed it to be appropriate to limit the number of claims that [Plaintiff] could assert, they cannot reasonably complain that they were required to similarly streamline their asserted references."); Ex. 1 (Eastern District of Texas, [Model] Order Focusing Patent Claims and Prior Art to Reduce Costs) at 2 (requiring patentee to elect claims and defendant to then limit to six prior art references per patent).

Beyond that, Regeneron opposes any other changes to any dates in the Scheduling Order, which Mylan only vaguely alludes to. Mot. 9-10. Mylan's motion fails to demonstrate good cause to delay the schedule, and Mylan's repeated violations of the Scheduling Order foreclose any further delays that would only reward Mylan's flagrant abuse of the Order.

Diligence. As Mylan acknowledges (Mot. 4), Federal Rule of Civil Procedure 16(b)(4) provides that "[a] schedule may be modified only for good cause and with the judge's consent." And "the good-cause standard will not be satisfied if the court concludes that the party seeking relief . . . has not acted diligently in compliance with the schedule." *Cook v. Howard*, 484 F. App'x 805, 815 (4th Cir. 2012) (quoting 6A Wright & Miller, *Federal Practice and Procedure Civ.3d* § 1522.2 (3d ed.2010)). Mylan's three blown expert report deadlines preclude a finding of diligence here. Mylan first served an opening expert report one week late, without notice to Regeneron or the Court. Rather than burdening the Court about Mylan's violation, Regeneron conferred with Mylan, and the parties agreed to extend the due date for Regeneron's response to Mylan's untimely report by five days. Second, Mylan served an expert report one month late

unveiling a new “prior commercial use” defense that Mylan failed to plead as an affirmative defense or disclose during discovery. This necessitated Regeneron’s motion to exclude Mylan’s new defense as waived and untimely, ECF 342-2. Mylan (rightly) did not even seek to defend this conduct, and instead agreed not to raise the defense at trial, thus mooted Regeneron’s motion to exclude. ECF 362. Third, and most recently, Mylan served a noninfringement report four weeks late, which should have been served with Mylan’s responsive expert reports on March 2. Mylan has not provided any explanation for this latest violation, which deprived Regeneron of an opportunity to serve a reply report. Nor has Mylan ever sought leave from the Court to serve any untimely reports. Mylan instead simply has pretended as if the deadlines in the Court’s Scheduling Order apply only when they are convenient for Mylan.

Such conduct precludes the diligence necessary to show good cause to modify a Scheduling Order. Mylan should not be rewarded for its three self-granted extensions with a further, unspecified extension from the Court. *See Tyndall v. Maynor*, 288 F.R.D. 103, 109 (M.D.N.C. Jan. 7, 2013) (finding lack of diligence and refusing to modify schedule where party “had not timely served expert reports” and instead sought “post-hoc extension of the expert report deadline, as well as a related extension of the overall discovery deadline”).

Remarkably, Mylan’s motion does not even address its untimely reports, and instead points only to the volume of reports it has served. Mot. 8. But numerosity cannot excuse Mylan’s repeated untimely expert reports. Mylan did not comply with *a single one* of the expert report deadlines in this case, and that precludes a finding of diligence.

Prejudice. Regeneron welcomes the further crystallization of issues before trial (Mot. 8), which is why Regeneron’s proposal requires both parties to narrow in the coming weeks (with Regeneron going first). However, Regeneron would be prejudiced by a requirement of

additional unilateral narrowing before the date required in the Scheduling Order, while Mylan may continue to leave its actual defenses at trial a mystery. Mylan presents a false choice between the Schedule and narrowing this case (Mot. 9), and absolves itself without basis from the burden of crystallizing issues. That burden belongs to both parties, *see Allergan*, 2017 WL 373462, at *3, and Mylan must do its part as well.

* * *

Mylan also requests a status conference to “assess the feasibility of proceeding to trial” on the date in the Scheduling Order. Should the Court wish to convene a status conference at its convenience, Regeneron stands ready to discuss its concrete narrowing proposal and any of the issues above.

Date: April 12, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on April 12, 2023, I electronically transmitted the foregoing with the Court. Counsel of record for all parties will be served by the Court's CM/ECF system.

/s/ Steven R. Ruby _____

Steven R. Ruby

EXHIBIT 1

Case No.: _____

Plaintiff,

v.

Defendant.

**[MODEL] ORDER FOCUSING
PATENT CLAIMS AND PRIOR ART
TO REDUCE COSTS**

The Court ORDERS¹ as follows:

1. This Order supplements all other discovery rules and orders. It streamlines the issues in this case to promote a “just, speedy, and inexpensive determination” of this action, as provided by Federal Rule of Civil Procedure 1.

Phased Limits on Asserted Claims and Prior Art References

2. By the date set for completion of claim construction discovery pursuant to P.R. 4-4, the patent claimant shall serve a Preliminary Election of Asserted Claims, which shall assert no more than ten claims from each patent and not more than a total of 32 claims. Not later than 14 days after service of the Preliminary Election of Asserted Claims, the patent defendant shall serve a Preliminary Election of Asserted Prior Art, which shall assert no more than twelve prior art references against each patent and not more than a total of 40 references.²

¹ The parties are encouraged to discuss limits lower than those set forth in this Model Order based on case-specific factors such as commonality among asserted patents, the number and diversity of accused products, the complexity of the technology, the complexity of the patent claims, and the complexity and number of other issues in the case that will be presented to the judge and/or jury. In general, the more patents that are in the case, the lower the per-patent limits should be. In cases involving several patent families, diverse technologies, disparate claims within a patent, or other unique circumstances, absent agreement of the parties, the court will consider flexibly whether circumstances warrant expanding the limits on asserted claims or prior art references. The parties shall jointly submit any proposed modifications by the deadline for submission of proposed docket control or discovery orders, but in no event later than the deadline for service of initial disclosures.

² For purposes of this Order, a prior art instrumentality (such as a device or process) and associated references that describe that instrumentality shall count as one reference, as shall the closely related work of a single prior artist.

3. No later than 28 days before the service of expert reports by the party with the burden of proof on an issue, the patent claimant shall serve a Final Election of Asserted Claims, which shall identify no more than five asserted claims per patent from among the ten previously identified claims and no more than a total of 16 claims. By the date set for the service of expert reports by the party with the burden of proof on an issue, the patent defendant shall serve a Final Election of Asserted Prior Art, which shall identify no more than six asserted prior art references per patent from among the twelve prior art references previously identified for that particular patent and no more than a total of 20 references. For purposes of this Final Election of Asserted Prior Art, each obviousness combination counts as a separate prior art reference.

4. If the patent claimant asserts infringement of only one patent, all per-patent limits in this order are increased by 50%, rounding up.

Modification of this Order

5. Subject to Court approval, the parties may modify this Order by agreement, but should endeavor to limit the asserted claims and prior art references to the greatest extent possible. Absent agreement, post-entry motions to modify this Order's numerical limits on asserted claims and prior art references

must demonstrate good cause warranting the modification. Motions to modify other portions of this Order are committed to the sound discretion of the Court.³

³ This Order contemplates that the parties and the Court may further narrow the issues during pretrial proceedings in order to present a manageable case at trial.