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

REGENERON PHARMACEUTICALS, INC., *Plaintiff*, v. CELLTRION, INC., *Defendant*.	Civil Action No. 1:23-cv-89-TSK
REGENERON PHARMACEUTICALS, INC., *Plaintiff*, v. SAMSUNG BIOEPIS, CO., LTD., *Defendant*.	Civil Action No. 1:23-cv-94-TSK
REGENERON PHARMACEUTICALS, INC., *Plaintiff*, v. SAMSUNG BIOEPIS, CO., LTD., *Defendant*.	Civil Action No. 1:23-cv-106-TSK
REGENERON PHARMACEUTICALS, INC., *Plaintiff*, v. FORMYCON AG, *Defendant*.	Civil Action No. 1:23-cv-97-TSK

REGENERON'S RESPONSE TO DEFENDANTS' MOTION FOR EXPEDITED STATUS CONFERENCE

Defendants have moved for an expedited status conference seeking (1) to preclude Regeneron from filing an omnibus preliminary injunction brief addressing common issues between the Defendants and (2) to revise substantially the Court's schedule for preliminary injunction proceedings on the eve of Regeneron's opening brief. D.I. 100. As to the first issue, Regeneron disagrees with Defendants' position, which will create unnecessary repetition in the briefing of issues common to multiple Defendants. Regeneron would accept a solution analogous to the one set forth in Defendants' recent response (No. 23-cv-97, D.I. 89) to "serve on each PI Defendant a copy of its omnibus [brief] redacting confidential and OCEO information from the other PI Defendants simultaneously with Regeneron's filing of its [brief] under seal." D.I. 89 at 5. This solution has the advantages of streamlining the presentation of issues to the Court with all the evidence and argument for each issue in one place, rather than distributed across three briefs. Regeneron—subject to the Court's preference—is also willing to file separate motions against each Defendant.

As to the second issue, however, Regeneron opposes Defendants' belated effort to alter the schedule the Court entered and restructure the Court's schedule to Regeneron's prejudice. Defendants had an opportunity to propose a preliminary injunction schedule last month (*e.g.*, No. 23-cv-89, D.I. 59) in response to Regeneron's motion regarding the issue (*id.*, D.I. 45), but their proposed schedule was rejected. Now, just over a week before Regeneron intends to file its motions for preliminary injunction and more than a month after the Court entered the schedule (*id.*, D.I. 83), is too late. Moreover, Defendants' proposal to restructure preliminary injunction briefing is supported by no authority and badly misapprehends the standard for a preliminary injunction in seeking to deprive Regeneron of the opportunity to address validity in its opening brief.

I. DEFENDANTS' BELATED EFFORT TO REVISE THE PRELIMINARY INJUNCTION SCHEDULE SHOULD BE DENIED

Citing no authority, Defendants propose a new schedule seeking to limit Regeneron to the issues of infringement and irreparable harm in its opening brief and to grant themselves advanced leave to file a surreply. D.I. 100 at 4-5. Unbelievably, Defendants do so without acknowledging that they previously proposed (without prior notice to Regeneron, during the course of the hearing) a schedule that included a surreply, No. 23-cv-89, D.I. 59-1, which this Court rejected in favor of the schedule Defendants seek to avert again. Beyond its untimeliness and the prejudice Defendants' proposed schedule would create by limiting unduly the arguments Regeneron may advance in its principal brief, Defendants also seek, arbitrarily and unfairly, to reduce the time for Regeneron to depose Defendants' declarants and prepare its reply. The Court should reject Defendants' drastic and untimely revisions to its duly considered schedule.

Defendants' proposed new schedule is premised on their assertion that they "bear the burden of proof" on "invalidity issues." D.I. 100 at 5. While Defendants do bear the ultimate burden of proving invalidity, in the relevant preliminary injunction context here, "a patentee must show that it will likely prove infringement of the asserted claims *and that its infringement claim will likely withstand the alleged infringer's challenges to patent validity* and enforceability." *Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1363-64 (Fed. Cir. 2017) (emphasis added). Accordingly, opening briefs seeking preliminary injunctions regularly address validity. *E.g.*, Ex. 1, *Automated Merch. Sys. Inc. v. Crane Co.*, No. 08-cv-97-JPB-JES, D.I. 19, at 15 (N.D.W. Va. July 29, 2008); Ex. 2, *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 17-cv-7111, D.I. 156, at 16 (D.N.J. July 31, 2018); Ex. 3, *BlephEx, LLC v. Myco Indus., Inc.*, No. 19-cv-13089, D.I. 10, at 17 (E.D. Mich. Nov. 7, 2019). Regeneron intends to meet its burden to show that it is likely to succeed at trial, including by addressing the relevance of the Court's decision in *Regeneron*

Pharm., Inc. v. Mylan Pharm. Inc., 2024 WL 382495 (N.D.W. Va. Jan. 31, 2024) upholding the validity of U.S. Patent 11,084,865, which Regeneron asserts here against each Defendant. Defendants' untimely effort to hamstring Regeneron's opening brief should thus be denied on this basis alone.

The propriety of addressing validity at the outset is even more appropriate here than in a typical patent case, both because the validity of the '865 patent already has been adjudicated by this Court in the Mylan action and because the Defendants already have served contentions regarding infringement and validity for each patent on which Regeneron may seek a preliminary injunction. Under the BPCIA's pre-suit provisions, applicants seeking approval of a biosimilar product (e.g., Defendants) are required to provide the owner of the reference product (e.g., Regeneron) with "a *detailed statement* that describes, on a claim by claim basis, the factual and legal basis of the opinion of the [Defendant] that such patent is invalid, unenforceable, or will not be infringed" by its proposed biosimilar product." 42 U.S.C. § 262(l)(3)(B)(ii) (emphasis added). While Defendants' pre-suit contentions are not technically binding, they are doubtlessly informative of the validity issues the Court may address in resolving Regeneron's injunction motions; indeed, when Regeneron asked Defendants to identify the validity arguments they intended to advance in opposing injunctive relief, they all refused. *See* Ex. 4 at 2 (Email to Celltrion); Ex. 5 at 1–2 (Email to Formycon); Ex. 6 at 3 (Email to Samsung).

Accordingly, Regeneron intends to address the validity allegations Defendants have advanced, on the basis of the contentions Regeneron possesses—the pre-suit contentions. Remarkably, in order to shield their own assertions from the Court, Defendants have taken the position—never adopted by any Court and contrary to the clear language of the statute—that the BPCIA somehow prevents Regeneron from submitting Defendants' BPCIA validity contentions,

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