

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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

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

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT’S MOTION  
FOR LEAVE TO AMEND ITS ANSWER, DEFENSES, AND COUNTERCLAIMS**

Defendant Mylan Pharmaceuticals Inc. (“Mylan”) brings this Motion seeking leave to amend its Answer, Defenses, and Counterclaims to add a declaratory judgment counterclaim of no lost profits or injunctive relief with respect to certain patents. Mylan’s Motion is being brought within the timeframe allotted by the Court’s Scheduling Order. (Dkt. No. 87). Thus, this Motion is subject to the general rule that the Court should “freely give leave when justice so requires.” Fed. R. Civ. P. 15(a)(2).<sup>1</sup>

**I. BACKGROUND.**

During the patent dance, Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Mylan

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<sup>1</sup> As a courtesy, Mylan requested Regeneron’s consent to file its Motion and provided a draft to Regeneron for its review. Regeneron responded that it “disagrees that Mylan’s new allegations have any merit, and it reserves the right to seek judgment on the pleadings at an appropriate juncture in the case. With that caveat, Regeneron does not oppose Mylan’s filing of its amended pleading.”

collectively identified a total of twenty-five (25) patents on the lists exchanged pursuant to 42 U.S.C. § 262(l)(5)(B)(i). Within thirty (30) days of completion of the patent dance, on August 2, 2022, Regeneron brought an action against Mylan alleging infringement of twenty-four (24) patents pursuant to 42 U.S.C. § 262(l)(6). (Dkt. No. 1).

After Mylan filed its Answer and Counterclaims, on October 28, 2022, Regeneron filed a stipulation unilaterally “elect[ing] six patents from three patent families to proceed in the first stage of litigation.” (Dkt. No. 88, at 1). The stipulation did not contain any details with regard to when the parties would litigate or otherwise resolve the patent disputes with respect to the unselected patents-in-suit. Under the current schedule, the start of any litigation with respect to these unselected patents will occur well after the statutory 30-day window to commence litigation under 42 U.S.C. § 262(l)(6).

In view of Regeneron’s actions to deprive Mylan of a full and fair opportunity to immediately litigate or otherwise resolve all of the patents-in-suit, Mylan hereby seeks leave to amend its responsive pleading to limit any relief with respect to infringement of these unselected patents that have been effectively dismissed without prejudice and/or not prosecuted to judgment in good faith under the Biologics Price Competition and Innovation Act (“BPCIA”).

## **II. ARGUMENT.**

Under Federal Rule of Civil Procedure 15, a party may amend its pleading “with the opposing party’s written consent or the court’s leave . . . [which] should freely give leave when justice so requires.” Fed. R. Civ. P. 15(a)(2). The Fourth Circuit has held consistently that a motion to amend a pleading should be denied “only when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would have been futile.” *Laber v. Harvey*, 438 F.3d 404, 426 (4th Cir. 2006); *see also Rich CoChran Levin v. Baron*, No. 1:12CV12, 2016 WL 6811083, at \*3 (N.D.W. Va. Jan. 15, 2016)

(granting parties' motion to amend counter-complaint, finding that despite adding a cause of action, "it is based on the same contracts, the same central facts, and . . . [the opposing parties] were fully aware of the events surrounding this action and its claims, and cannot be surprised."). None of these factors are applicable here.

First, Regeneron will not be prejudiced by Mylan's proposed amendment. As an initial matter, this Court's Scheduling Order permits the parties to file motions to amend pleadings by or before December 9, 2022, (Dkt. No. 87), and Mylan's amendment would not impact the Court's expedited schedule as this is a purely legal issue that does not require any additional discovery. Furthermore, from the outset, Regeneron has been fully aware of Mylan's position that the parties should litigate or otherwise resolve the patent dispute related to all 24 patents-in-suit as contemplated by the BPCIA. (*See e.g.*, Dkt. Nos. 26, 75). Likewise, immediately following the September 29, 2022 Status Conference, Mylan filed a post-hearing supplement setting forth its position that any remedy for infringement of the unselected patents be limited to a reasonable royalty—this is the same argument that is the basis of Mylan's proposed counterclaim. (Dkt. No. 77). Thus, Regeneron is not unfairly disadvantaged and will not be deprived of any opportunity to oppose Mylan's interpretation of the BPCIA.

Second, Mylan's motion to amend is not made in bad faith, with undue delay, or with dilatory motive. Mylan is timely seeking to add this counterclaim to ensure that Regeneron's voluntary and one-sided decision to limit the asserted patents, with no plan or agreement to resolve the remaining patents, is consistent with the remedies contemplated by the BPCIA under such circumstances. As noted above, this motion for leave to amend is made within the permitted timeframe under the Scheduling Order and is filed within six weeks of Regeneron's unilateral narrowing of the patents-in-suit to six patents. Mylan has a legitimate interest in seeking to limit

the infringement remedies available for the unselected patents and has acted reasonably to ensure Regeneron is timely aware of the bases for Mylan's claim.

Third, Mylan's proposed counterclaim is not futile as it alleges specific, individualized facts and legal bases to support its interpretation of the BPCIA and the claim of relief it seeks. This counterclaim is necessary and proper and directly arises out of the parties' pre-suit exchanges and Regeneron's unilateral actions to narrow the patents under the circumstances here.

### **III. CONCLUSION.**

For at least the foregoing reasons, Mylan respectfully requests that its Motion for Leave to Amend Its Answer, Defenses, and Counterclaims be granted.

Dated: December 9, 2022

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**CERTIFICATE OF SERVICE**

I hereby certify that, on this the 9th day of December 2022, I filed the foregoing “Memorandum of Law In Support of Defendant’s Motion For Leave to Amend Its Answer, Defenses, and Counterclaims” with the Clerk of the Court using the Court’s CM/ECF system, which will send notification of the same to all counsel of record.

*/s/ William J. O’Brien*

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