

**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  
ALTERNATIVE SUBMISSION REGARDING CLAIM CONSTRUCTION**

Regeneron has no objection to Mylan filing an additional submission regarding claim construction. The Court should have the full benefit of the parties' positions and explanations, and in any event, Mylan's "Alternative Submission" (ECF 261) reinforces that Mylan's experts agreed with Regeneron's positions, not Mylan's, as to the legally salient issues such as the patent's repeated disclosure that polysorbate is an organic co-solvent. At the claim construction hearing, Regeneron will be prepared to address the substance of Mylan's position, which squarely violates the Federal Circuit's repeated guidance that expert testimony is "less reliable" than, and cannot contradict, the patent specification.

Regeneron responds briefly, however, to Mylan's accusation that Regeneron's five-and-a-half-page submission summarizing Mylan's declarant testimony was "uninvited, unauthorized," and improper. ECF 261 at 1. To the contrary, it was Mylan's refusal to make its declarants promptly available for deposition that warranted Regeneron's notice. ECF 226-1.

On November 29, Mylan filed its opening claim construction brief. That brief made apparent that Mylan was advancing claim constructions devoid of support in the patents

themselves and instead reliant almost exclusively on extrinsic evidence, *i.e.*, the declarations of Dr. MacMichael (addressing the Formulation Patent) and Dr. Jungbauer (addressing the Manufacturing Patent). Two days later, on December 1, Regeneron requested the availability of Drs. MacMichael and Jungbauer for deposition in advance of the parties' responsive briefs due December 16. Ex. 1 at 2-3 (Dec. 1, 2022 Regeneron Email). Mylan declined to make its experts available during that period and thereby precluded Regeneron from addressing their sworn testimony in its responsive claim construction brief. Ex. 1 at 2 (Dec. 2, 2022 Mylan Email). Accordingly, Regeneron explained, long in advance of submitting its responsive claim construction brief, that if Mylan refused to make its declarants available for deposition in time for the parties' responsive briefs, then Regeneron would submit a short supplemental brief addressing deposition testimony thereafter. Ex. 1 at 1 (Dec. 5, 2022 Regeneron Email). That is exactly what Regeneron did. ECF 226. Mylan's characterizations of Regeneron's filing are without merit.

Date: January 23, 2022

CAREY DOUGLAS KESSLER & RUBY, PLLC

*Of Counsel:*

David I. Berl (admitted *PHV*)  
 Ellen E. Oberwetter (admitted *PHV*)  
 Thomas S. Fletcher (admitted *PHV*)  
 Andrew V. Trask (admitted *PHV*)  
 Teagan J. Gregory (admitted *PHV*)  
 Shaun P. Mahaffy (admitted *PHV*)  
 Sean M. Douglass (admitted *PHV*)  
 Kathryn S. Kayali (admitted *PHV*)  
 Arthur J. Argall III (admitted *PHV*)  
 Adam Pan (admitted *PHV*)  
 Nicholas Jordan (admitted *PHV*)  
 Haylee Bernal Anderson (admitted *PHV*)  
 Renee Griffin (admitted *PHV*)

/s/ Steven R. Ruby

Steven R. Ruby (WVSB No. 10752)  
 David R. Pogue (WVSB No. 10806)  
 707 Virginia Street East  
 901 Chase Tower (25301)  
 P.O. Box 913  
 Charleston, West Virginia 25323  
 (304) 345-1234  
 sruby@cdkrlaw.com  
 drpogue@cdkrlaw.com

WILLIAMS & CONNOLLY LLP  
680 Maine Avenue, SW  
Washington, DC 20024  
(202) 434-5000  
dberl@wc.com  
eoberwetter@wc.com  
tfletcher@wc.com  
atrask@wc.com  
tgregory@wc.com  
smahaffy@wc.com  
sdouglass@wc.com  
kkayali@wc.com  
aargall@wc.com  
apan@wc.com  
njordan@wc.com  
handerson@wc.com  
rgriffin@wc.com

Andrew E. Goldsmith (admitted *PHV*)  
Evan T. Leo (admitted *PHV*)  
Jacob E. Hartman (admitted *PHV*)  
Mary Charlotte Y. Carroll (admitted *PHV*)  
Sven E. Henningson (admitted *PHV*)  
KELLOGG, HANSEN, TODD, FIGEL &  
FREDERICK, P.L.L.C.  
1615 M Street, N.W., Suite 400  
Washington, D.C. 20036  
TEL: (202) 326-7900  
agoldsmith@kellogghansen.com  
eleo@kellogghansen.com  
jhartman@kellogghansen.com  
mcarroll@kellogghansen.com  
shenningson@kellogghansen.com

**CERTIFICATE OF SERVICE**

I hereby certify that on January 23, 2023 I electronically transmitted the foregoing with the Court. Counsel of record for all parties will be served by the Court's CM/ECF service.

/s/ Steven R. Ruby

Steven R. Ruby