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**

NOTICE OF SUPPLEMENTAL AUTHORITY REGARDING CLAIM CONSTRUCTION

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") provides this Notice of Supplemental Authority to inform the Court of a March 10, 2023 decision of the Patent Trial and Appeal Board ("PTAB") involving one of the patents asserted by Regeneron in this case against Mylan. In that decision, the PTAB declined to institute an *inter partes* review of U.S. Patent No. 11,253,572 (the "'572 Patent") following a request by another biosimilar company, Apotex Inc. *See* Exhibit A, *Apotex Inc. v. Regeneron Pharmaceuticals, Inc.*, IPR2022-01524, Paper 9. The PTAB found that Apotex had "not demonstrate[d] a reasonable likelihood of prevailing at trial" on the challenged claims of the '572 Patent, and so institution of an IPR was not warranted. Ex. A, at 39. Subject to reconsideration by the PTAB, that decision is final and non-appealable.

As relates to the claim construction issues that are pending before the Court, the PTAB rejected the argument Mylan is advancing that claim limitations in the '572 Patent directed to the measurement of gains in visual acuity lack patentable weight. *See, e.g.*, Dkt. 306, ¶¶ 151-57 (Mylan Proposed FF&CL); Dkt. 313-2, ¶¶ 76-79 (Regeneron's responsive arguments in its Corrected Proposed FF&CL). The PTAB found that "the results limitations of the claims are limitations and must be given patentable weight." Ex. A, at 27 (itals. omitted). The PTAB relied

in part on *Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center v. Eli Lilly & Co.*, 849 F.3d 1049 (Fed. Cir. 2017), in which the Federal Circuit reversed the district court and held that limitations in a method of treatment claim of "arresting or regressing" tissue fibrosis had a limiting role. Ex. A, at 16-17; *see also* Dkt. 313-2, ¶ 78 (Regeneron Corrected Proposed FF&CL) (discussing the *Los Angeles Biomedical Research Institute* case). The PTAB found the claims in *Los Angeles Biomed* to be analogous to the visual acuity results limitations challenged in the '572 Patent. Ex. A, at 18 ("We find in agreement with Patent Owner that the *results limitations* of the challenged claims are limitations and must be given patentable weight for the same reasons *arresting or regressing a tissue fibrosis* was a limitation in *Los Angeles Biomed*.") (itals. in original). Similar language appears in some of the claims of U.S. Patent No. 10,888,601 (the "'601 Patent"), and the same analysis should apply to those claims.

As Regeneron has explained, decisions of the PTAB are not binding on this Court, and the Court need not interpret or assess the patentable weight of the visual acuity limitations of the '572 Patent's claims to interpret the phrase actually designated for claim construction, which is "Best Corrected Visual Acuity." Dkt. 313-2, ¶¶ 76, 79. Regeneron nevertheless provides the PTAB's decision to the Court, given that Mylan previously submitted and relied heavily upon a preliminary institution decision that the PTAB made as to the '601 Patent. *See* Dkt. 254.

Date: March 13, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 13, 2023, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

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