UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., CELLTRION, INC., and APOTEX, INC.,
Petitioners

v.

REGENERON PHARMACEUTICALS, INC.
Patent Owner

Case IPR2021-00881[1]
Patent 9,254,338 B2

RESPONSE TO PETITIONER'S IDENTIFICATION OF STATEMENTS SUPPORTED BY OBJECTED TO REFERENCES IN PATENT OWNER RESPONSES

[1] IPR2022-00258 and IPR2022-00298 have been joined with this proceeding.

In accordance with the Board's order during the teleconference held on February 23, 2022, Patent owner hereby submits its response to Petitioner's Identification of Statements Supported by Objected to References in Patent Owner Responses. Paper No. 44; *see also* Ex. 1100 Transcript of Teleconference Proceedings held on February 23, 2022, at 16:22-19:7.

Petitioner's Challenge	**Patent Owner Response—Arguments and Evidence**
IPR2021-00881, Patent No. 9,254,338 • Paper 40 (POR) • Section VIII.B, (Paper 40, pp. 58-62, entitled "Objective Evidence Confirms the Non-Obviousness of the Claimed Dosing Regimen"). • Ex. 2051, Do Decl. ¶¶98-133, 135-170	**Nexus**—Paper 40, pp. 58-60; *see, e.g.*, *id.*, p. 59 ("A nexus exists between the Challenged Claims and both EYLEA®'s approved dosing regimen (the "Eylea Label" or "EL") and physicians' administration of EYLEA in practice ("Physicians' Practice" or PP, and together with EL, "EL&PP")"); *id.*, 58-59 (chart arguing that a nexus exists between each limitation of each challenged claims and the Eylea Label, Physicians' Practice, or both). *See also* Ex. 2051 (Do Decl.), ¶¶98-133 (the United States prescribing information for Eylea demonstrates practice of the challenged claims); *id.*, ¶¶134-170 (physicians' administration of Eylea to patients practices the challenged claims).
IPR2021-00881, Patent No. 9,254,338 • Paper 40 (POR) • Section I, (Paper 40, pp. 1-3, entitled "Introduction"). • Section VIII.B, (Paper 40, pp. 54, 58-62 entitled "Objective	**Commercial success**—Paper 40, pp. 1-3, 54, 58-62; *see, e.g.*, *id.*, p. 1. ("Despite launching into a competitive market, EYLEA quickly became the preeminent treatment for angiogenic eye disorders including wAMD, diabetic macular edema, macular edema following retinal vein occlusion, and diabetic retinopathy."); *id.*, p. 2 ("EYLEA has enjoyed rapid clinical adoption and great commercial success."); *id.*, pp. 61-62 ("Regeneron's U.S. sales of EYLEA, as well as EYLEA's share of sales relative to other anti-VEGF treatments, have grown significantly

Petitioner's Challenge	Patent Owner Response—Arguments and Evidence
Evidence Confirms the Non-Obviousness of the Claimed Dosing Regimen"). • Ex. 2052, Manning Decl. ¶¶29-42, 48-117	since launch."); *id*.("[T]he '338 Patent's claimed dosing regimen has been an important factor driving demand for EYLEA."); *id*., n. 18 ("EYELA's commercial success does not appear to be due to marketing efforts…."). *See also* Ex. 2052 (Manning Decl.), ¶¶29-42 (treatment options for angiogenic eye disorders); *id*. ¶¶48-85 (Eylea was a commercial success); *id*., ¶¶89-104 (the claimed dosing regimen is a driver of the demand for Eylea); *id*., ¶¶105-117 (Eylea's commercial success cannot be explained by factors not related to the claimed methods of treatment).
IPR2021-00881, Patent No. 9,254,338 • Paper 40 (POR) • Section VIII.B, (Paper 40, pp. 58-62, entitled "Objective Evidence Confirms the Non-Obviousness of the Claimed Dosing Regimen"). • Ex.2050, Brown Declaration ¶¶150-181	**Long-felt but unmet need, failure of others, unexpected benefit, and industry praise**—Paper 40, pp. 1-6, 13, 53-54, 58-62; *see, e.g.*, *id*., p. 54 ("[T]he long-felt need and failure in the art to develop an extended dosing regimen … confirm the non-obviousness of the claimed dosing regimen."); *id*., 60-62 ("[T]he art was littered with failed efforts to extend dosing of anti-VEGF agents, which made Regeneron's clinical trial results all the more unexpected."); *id*. pp. 3-6 ("Numerous attempts were made to decrease injection or monitoring frequency with ranibizumab, including the PIER, PrONTO, SAILOR, EXCITE, and SUSTAIN clinical trials. Each of these efforts at extended dosing in the art failed ….") (internal citations omitted); *id*., p. 13 ("[T]here remained a need in the art to reduce the burden of frequent injections and monitoring visits while maintaining the high level of efficacy…."). *See also* Ex. 2052 (Brown Decl.), ¶¶45, 75-85, 156-176 (satisfaction of a long felt but unmet need); *id*., ¶¶46-69, 110-113; 160-173: (failure of others); *id*., ¶¶75-90, 174-181 (unexpected benefits and industry praise).

Petitioner's Challenge	Patent Owner Response—Arguments and Evidence
IPR2021-00880, • Paper 39 (POR) • Section V, (Paper 39, pp. 7-9, entitled "Claim Construction") • Section V, (Paper 39, p. 8 n. 5)	**Claim construction**—Paper 39, pp. 7-9, n. 5; *see, e.g.*, *id.*, p. 8 (Claim construction "is not necessary to resolve the arguments presented in Mylan's Petition."); *id.*, n. 5 ("[I]f the Board decides to construe 'method of treating' or "tertiary dose' in this IPR, it should do so consistently with the constructions Regeneron has proposed in its contemporaneously filed Response in IPR2021-00881 relating to the '338 Patent, since the '069 Patent was filed as a continuation from the '338 Patent.) (citing *Samsung Elecs. Co. v. Elm 3DS Innovations, LLC*, 925 F.3d 1373, 1378 (Fed. Cir. 2019)).

Dated: March 3, 2022

Respectfully Submitted,

/s/ Deborah E. Fishman
Deborah E. Fishman (Reg. No. 48,621)
3000 El Camino Real #500
Palo Alto, CA 94304

Counsel for Patent Owner,
Regeneron Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4)(i) *et seq*. and 42.105(b), the undersigned Certifies that on March 3, 2022, a true and entire copy of this **RESPONSE TO PETITIONER'S IDENTIFICATION OF STATEMENTS SUPPORTED BY OBJECTED TO REFERENCES IN PATENT OWNER RESPONSES** was served via e-mail to the Petitioner at the following email addresses:

MYL_REG_IPR@rmmslegal.com
paul@ rmmslegal.com
wrakoczy@ rmmslegal.com
hsalmen@ rmmslegal.com
nmclaughlin@rmmslegal.com
lgreen@wsgr.com
ychu@wsgr.com
rcerwinski@geminilaw.com
azalcenstein@geminilaw.com
bmorris@geminilaw.com
TRea@Crowell.com
DYellin@Crowell.com
SLentz@Crowell.com

/s/ Deborah E. Fishman
Deborah E. Fishman (Reg. No. 48,621)
3000 El Camino Real #500
Palo Alto, CA 94304

Counsel for Patent Owner,
Regeneron Pharmaceuticals, Inc.