UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SLAYBACK PHARMA LLC,
Petitioner,

v.

EYE THERAPIES, LLC,
Patent Owner.

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Case No.: IPR2022-00142

U.S. Patent No.: 8,293,742

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PETITIONER'S REPLY SUPPLEMENTAL BRIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Petitioner respectfully submits this response to Patent Owner's Brief Addressing the Board's Questions (Paper 70, "PO Br.").

I. ISSUE #1: THE PREAMBLE AND INHERENT ANTICIPATION

A. The Preamble Limits the Claims but Does Not Require Efficacy

The parties do not dispute that the preamble phrase "for reducing eye redness" is a statement of intentional purpose for which the method must be performed. *See* PO Br. at 2–4. Patent Owner, however, asks the Board to go beyond the plain meaning of "for" and find that the preamble also requires "achiev[ing] the stated purpose of administrating brimonidine to a patient with ocular hyperemia—to reduce the eye redness" (i.e., efficacy). *Id.* at 5–6. This is improper.

Patent Owner asserts, without explanation, that efficacy is required because the preamble is "written with the gerund form of the verb." *Id.* at 5. Patent Owner, however, fails to address the Board's decision in *Mylan Pharms. Inc. v. Regeneron Pharms., Inc.*, No. IPR2021-00881, 2022 WL 16842073 (P.T.A.B. Nov. 9, 2022). There, the Board determined the preamble—"[a] method for treating an angiogenic eye disorder in a patient"—required the "therapeutic [be] administered with the 'intentional purpose' of treating an angiogenic eye disorder, without showing actual therapeutic effectiveness." *Id.* at *8–*9. The Board determined "it is the administration of the VEGF antagonist to such patient for the purpose of providing an improvement of or beneficial effect on their angiogenic eye disorder that satisfies

the 'treating' portion of the preamble." *Id.* The same conclusion applies here. "[F]or reducing eye redness" does not require the method to actually reduce eye redness.

The cases cited by Patent Owner do not change the plain meaning of "for reducing eye redness." *Jansen* focused on whether a limiting preamble was infringed. Even in that case, however, the Federal Circuit did not require efficacy to find infringement. Rather, infringement turned on intent: if the patients did not "take the Rexall product knowingly to treat or prevent macrocytic-megaloblastic anemia," then they would not infringe the patent. *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333–34 (Fed. Cir. 2003). In *Sanofi*, the Federal Circuit remanded to the Board because "[t]he Board erred by treating the preamble here as non-limiting." *Sanofi Mature IP v. Mylan Lab'ys Ltd.*, 757 F. App'x 988, 994 (Fed. Cir. 2019). In the Federal Circuit's view, the preamble in that case "expresse[d] the '***intentional purpose [increasing survival]***' for which the method must be performed." *Id.* at 993 (quoting *Jansen*, 342 F.3d at 1333) (emphasis added). Patent Owner goes too far when it suggests *Sanofi* endorsed an efficacy requirement.[1]

[1] Contrary to Patent Owner's assertion, Petitioner has not shifted positions. Petitioner always treated the preamble as a limiting statement of intentional purpose. The testimony from Dr. Sher on which Patent Owner relies did not "effectively conced[e] an efficacy requirement." PO Br. at 3. The portion of Dr. Sher's declaration cited by

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