UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC,

Petitioner,

v.

EYE THERAPIES, LLC,

Patent Owner.

Case IPR2022-00142
U.S. Patent No. 8,293,742

PATENT OWNER'S REPLY BRIEF ADDRESSING THE BOARD'S QUESTIONS

Table of Contents

TABLE OF AUTHORITIES

Page(s)

Cases

I. Question 1: The Preamble and Inherent Anticipation

A. The preamble requires redness reduction

There is no dispute that the preamble—a method for reducing eye redness—is limiting. Instead, the parties dispute whether the preamble requires reduction of ocular hyperemia as Patent Owner contends (Paper 71 at § II.A), or merely *mens rea* regarding reducing redness without any effectiveness as Petitioner contends (Paper 70 at § I.A). Petitioner's position is inconsistent with the claims themselves, intrinsic record, and Federal Circuit precedent.

It is undisputed that the Federal Circuit's decision in *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331 (Fed. Cir. 2021) is instructive. Paper 70 at 2-3. The Federal Circuit's guidance in *Eli Lilly* and *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329 (Fed. Cir. 2003) support construing the preamble to require redness reduction. *See* Paper 71 at § II.A. Indeed, as in *Eli Lilly* and *Jansen*, the intrinsic record of the '742 patent emphasizes the essence of the invention—use of low dose brimonidine to reduce redness. *See e.g.*, EX-1001 at 2:38-41, 4:26-30. Moreover, despite Petitioner's suggestion to the contrary (Paper 70 at 2-3, n.1), the language in the '742 patent claims nearly parallels the language central to the court's decision in *Jansen*. Like *Jansen* where the claims recited "treating or preventing" a condition "to a human in need thereof," here, the claims recite "reducing eye redness" "to a patient having an ocular condition." 342 F.3d at 1332-34; *see Sanofi Mature IP v.*

Mylan Lab'ys Ltd., 757 F. App'x 988, 994 (Fed. Cir. 2019) (akin to *Jansen*, the preamble "[a] method of increasing survival" requires increasing survival).

Mylan Pharms. Inc. v. Regeneron Pharms., Inc., No. IPR2021-00881, 2022 WL 16842073 (P.T.A.B. Nov. 9, 2022) is inapposite. The Board's conclusion in *Mylan* turned on facts not present here. *See id.* at *9. For context, the claims in Mylan were directed to a sequential dosage regimen (i.e., timing of doses), where it was undisputed that the method of using the compounds at issue (VEGF antagonists) for the claimed use (treating angiogenic eye disorders) was known. *Id.* at *3. The claims did ***not*** recite any concentrations of the VEGF antagonists, but rather focused only on timing of dosing. *Id.* at *9. Additionally, the preamble recited "treating a patient with an angiogenic eye disorder," akin to administering the compound, without requiring (or even describing) a specific result in the claims. *Id.* The facts here are materially different from those in *Mylan*. As an example, there is no such concession about the method of use being known in the art. In fact, the inventors surprisingly discovered that low-dose brimonidine could work to reduce redness, and therefore claimed use of specific doses of brimonidine—"between about 0.001% . . . and about 0.05%" and "between about 0.001% to about 0.025%"—for reducing eye redness. EX-1001 at claims 1-3. Because the facts and claim language central to the decision in *Mylan* are not present here, Petitioner's reliance on this case is misplaced.

B. Even if the Preamble Only Requires an Intent to Reduce

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