

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ELI LILLY AND COMPANY,  
Petitioner,

v.

LOS ANGELES BIOMEDICAL RESEARCH INSTITUTE AT  
HARBOR-UCLA MEDICAL CENTER,  
Patent Owner.

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Case IPR2014-00752  
Patent 8,133,903

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Before FRANCISCO C. PRATS, SHERIDAN K. SNEDDEN, and  
SUSAN L. C. MITCHELL, Administrative Patent Judges.

ORDER  
Denying Patent Owner's Motion to Strike  
*37 C.F.R. § 42.5*

## I. INTRODUCTION

With our prior authorization (Paper 79), Patent Owner filed a Motion to Strike (Paper 81; “Mot.”) seeking to strike portions of Petitioner’s Reply (Paper 73; “Reply”), portions of Dr. Goldstein’s Reply Declaration (Ex. 1153), portions of Ex. 1002, and portions of Ex. 1151. Mot. 1–2.

Petitioner filed an Opposition to Patent Owner’s Motion to Strike. Paper 83 (“Opp.”).

Based on our consideration of the parties’ positions, we deny Patent Owner’s Motion to Strike for the reasons that follow.

## II. DISCUSSION

The Board recently issued guidance in the form of a “Trial Practice Guide Update,” dated August 2018 (“Practice Guide”). *See* 83 Fed. Reg. 38,989 (Aug. 13, 2018) (notifying the public of the updated “Practice Guide” and its accessibility through the USPTO website: <https://go.usa.gov/xU7GP>). With regard to motions to strike, the Practice Guide provides the option to request authorization to file a motion “[i]f the party believes that a brief filed by the opposing party raises new issues, is accompanied by belatedly presented evidence, or otherwise exceeds the proper scope of reply or sur-reply.” Practice Guide 17. Specifically, the Practice Guide addresses the distinct applicability of these two alternatives:

A motion to strike may be appropriate when a party believes the Board should disregard arguments or late-filed evidence in its entirety, whereas further briefing may be more appropriate when the party wishes to address the proper weight the Board should give to the arguments or evidence. In most cases, the Board is capable of identifying new issues or belatedly presented evidence when weighing the evidence at the close of trial, and disregarding any new issues or belatedly presented evidence that exceeds the

proper scope of reply or sur-reply. As such, striking the entirety or a portion of a party's brief is an exceptional remedy that the Board expects will be granted rarely.

*Id.*

Patent Owner contends that Petitioner's Reply introduces two new theories and evidence to support those two new theories. Mot. 1. Patent Owner contends that Petitioner's Reply introduces a first new theory because Petitioner "tries to redefine "fibrosis" by advancing a new theory it calls 'collagen remodeling.'" Mot. 1. Patent Owner contends that "[t]he 'collagen remodeling' theory is not responsive to arguments in [Patent Owner]'s supplemental response, nor to new claim constructions." *Id.* at 1–2 (citing Reply 6:10–8:11, 24:4–25:4, 25:10–26:3; Ex. 1153 ¶¶ 22–23, 25–27, 30–37, 39, 45, 49, 56; and Ex. 1002, 1169–72).

Patent Owner additionally contends that Petitioner's Reply "advances a [second] new theory that PDE-5 inhibitors 'amplify' NOS and the NO/cGMP pathway." Mot. 3–4 (citing Reply 12 (diagram), 13:3–10, 18:7–9, 18:16–19:7, 19:16–20:7, 23:4–15; Ex. 1153 ¶¶ 7–13, 17, 19–20, 50–56, 58, 60–63, 68; and Ex. 1002, 1169–72). Specifically, Patent Owner contends as follows:

The "amplification" theory is new. For example, although Lilly's reply argues 19 times that PDE-5 inhibitors "amplify" NOS and the NO/cGMP pathway, "amplify" does not appear in the petition even once. And although Dr. Goldstein attempts to anchor this theory in the petition by citing 17 paragraphs from his original declaration (Ex. 1153 ¶ 7 (citing Ex. 1089 ¶¶ 102–118)), in deposition he failed to identify any concrete support for the theory. Ex. 2117 at 61:19–64:3, 65:7–66:2, 69:15–70:18, 72:10–79:14 (discussing Ex. 1089 ¶¶ 106, 108, 113, 118).

*Id.* at 3.

Petitioner responds that it “relies on the same evidence and reasoning as the Petition to establish obviousness (e.g., Reply, 8-10) and is directly responsive to [Patent Owner]’s new arguments.” Opp. 1.

Having considered the parties’ positions and evidence of record, we agree with Petitioner. For example, in its Petition (Paper 1, “Pet.”), Petitioner argues that Ferrini 2002 taught that once formed fibrosis is “in a state of flux” such that “interventions aiming to reduce collagen deposition may be beneficial” as they can “counteract[] collagen deposition in PD plaque tissues.” Pet. 44. In response, Patent Owner argues in its Supplemental Patent Owner Response (Paper 63, “Supp. PO Resp.”) that Ferrini 2002 does not teach “arrest[ing] or regress[ing] . . . an already developed fibrosis” and further argues that Ferrini 2002 “do[es] not suggest or envision any role for what [Petitioner] calls the ‘nitric oxide pathway’ or the ‘NO/cGMP pathway’—i.e., for downstream mediators of NO such as cGMP—in penile fibrosis.” Supp. PO Resp. 36. In its Reply, Petitioner presents argument and evidence explaining how a person of ordinary skill in the art would have understood that the fibrotic plaque exists in a “state of flux” or “dynamic balance” due to continuous “collagen remodeling” by opposing collagen synthesis and degradation processes. Reply 6–7. Such evidence, “to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness,” is entirely proper. *Genzyme Therapeutic Prod. Ltd. P’ship v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1369 (Fed. Cir. 2016).

Similarly, in its Petition (Paper 1, “Pet.”), Petitioner argues that PDE5-inhibitors were a known “means for enhancing the penile NO/cGMP pathway,” i.e., “agents to increase nitric oxide and/or cGMP in a tissue.”

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Pet. 7–9. The argument and evidence identified by Patent Owner in its Motion further explain this theory expressed throughout the Petition and rebutted in the Supplemental Patent Owner Response. *Cf.* Pet. 6, 7–9, 43; Supp. PO Resp. 36, 38, 43; Reply 12 (diagram), 13:3–10, 18:7–9, 18:16–19:7, 19:16–20:7, 23:4–15. We also determine that Petitioner’s evidence submitted with its Reply merely supports the arguments made in the Reply, which is proper in an *inter partes* review. *Genzyme*, 825 F.3d at 1369.

Accordingly, we determine that Patent Owner has not met its burden to establish that Petitioner’s Reply is improper and we see no good cause to grant the rare remedy of striking the evidence as requested by Patent Owner.

Upon consideration thereof, it is

ORDERED that Patent Owner’s Motion to Strike is *denied*.

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