UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELI LILLY AND COMPANY,
Petitioner,

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH,
Patent Owner.

Case No. IPR2018-01710
Patent No. 8,586,045

PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO STRIKE

I. Introduction

Lilly's Reply, accompanying exhibits, and supporting declarations respond to new issues raised in Teva's POR and by Teva's experts and therefore are within the proper scope of a reply. Teva claims that Lilly's Reply and exhibits "present new evidence and theories of invalidity," but there is nothing to support those conclusory statements. Instead, Teva uses its Motion to argue its substantive validity positions and level unsupported attacks on Lilly's experts. Teva's Motion should be denied.

II. Argument

A petitioner in an IPR proceeding may introduce arguments at the reply stage in response to arguments raised in a POR. *Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1380-81 (Fed. Cir. 2018); 37 C.F.R. § 42.23(b). The Board routinely allows new evidence, including declarations from new experts, in reply. *See*, *e.g.*, *Belden Inc. v. Berk–Tek LLC*, 805 F.3d 1064, 1078 (Fed. Cir. 2015). New reply evidence is also appropriate if it is used "to document the knowledge that skilled artisans would bring to bear in reading the prior art identified as producing obviousness." *Anacor,* 889 F.3d at 1380-81.

Striking portions of a party's brief is "an exceptional remedy" not warranted here. *See* Trial Practice Guide Update, 17-18 (August 2018). A reply or reply evidence may be excluded if it introduces an entirely new theory of obviousness or new evidence that is necessary to make out a *prima facie* case of patentability.

Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1369-70 (Fed. Cir. 2016) ("*Illumina*"). By contrast, exclusion is inappropriate where, as here, a reply "expands the same argument made in its Petition." *Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1381 (Fed. Cir. 2018).

A. Exhibit 1287 and Related Sections of Lilly's Reply

Exhibit 1287 and Lilly's related argument (Reply, 6, 15) are directly responsive to assertions newly made in Teva's POR. Tan 1995 reports on the *in vivo* activity of anti-CGRP antibodies with defined specificity, known affinity, reproducibility, and unlimited availability. Pet. 16-17. Teva and its experts nevertheless incorrectly argued that Tan 1995, an asserted reference, was a "basic research paper" that would not have motivated a POSA to make humanized antibodies. POR, 2, 4, 14-15; Ex. 2268 ¶¶ 138, 140; Ex. 2265 ¶¶ 15, 83, 87, 92. Teva further alleged to have personal knowledge of co-authors of the Tan references, implying they never considered antibody humanization. Ex. 2268 ¶ 147. Teva also argued that certain blood pressure data presented in Tan 1995 would have discouraged further research. POR, 5, 27-28.

Exhibit 1287, which was written by Dr. Tan in 1994 and describes his and his co-authors' work in Tan 1995, directly contradicts Teva's arguments. With first-hand knowledge of the blood pressure results in Tan 1995, Dr. Tan wrote there was "no reason" why humanized anti-CGRP monoclonal antibodies should not be

investigated and used as "therapeutic agents" for migraine. Ex. 1287, 247; Reply, 15. Contradicting Teva's reliance on purported personal knowledge of Tan 1995's authors, Exhibit 1287 makes clear that Dr. Tan believed humanized anti-CGRP antagonist antibodies should be developed notwithstanding the blood pressure data Teva focused on in its POR. Exhibit 1287 is therefore proper reply evidence. Moreover, Lilly's use of Exhibit 1287 does not require it to qualify as a "printed publication," as Teva contends (although Teva's Motion fails to undermine public availability). *See* Mot., 2.

Contrary to Teva's argument, Exhibit 1287 is not "filling a hole" in Lilly's primary case. The *Illumina* decision relied on by Teva is illustrative. There, the petition asserted that there was motivation to *use* reaction conditions disclosed in *Zavgorodny* (a prior art reference). 821 F.3d at 1368-69. Reversing course, petitioner's reply asserted there was *no* motivation to use the *Zavgorodny* reaction conditions; rather, the reply argued one would modify the disclosure in *Zavgorodny*, citing an entirely new expert report and supporting evidence. *Id.*

Here, the Petition's strong case of obviousness stands on its own. Lilly's Reply maintains the same positions and relies on the same core prior art. The Reply uses Exhibit 1287 to correct Teva's post-hoc characterizations of Tan 1995 as well as Teva's allegation that the authors of Tan were not considering "targeting CGRP, much less targeting CGRP with an antibody for clinical use in human patients." Ex.

2268, ¶ 147. Since Teva created this inaccurate portrayal, it is only appropriate that Dr. Tan's own statements be allowed to correct the record. *Belden*, 805 F.3d at 1082 ("the function of rebuttal [is] to explain, repel, counteract, or disprove the evidence of the adverse party").

B. Dr. Balthasar's Declaration and Related Sections of Lilly's Reply

Teva raised new arguments related to antibody distribution to the synaptic cleft (POR, 36-37; Ex. 2265, ¶¶ 82-91), and now incorrectly seeks to strike portions of Lilly's Reply and Dr. Balthasar's declaration addressing this issue (Reply, 10-11; Ex. 1337, ¶¶ 22, 24-25, 30-33).

Tan 1995 states that "IgG should eventually distribute to interstitial space and achieve . . . concentrations required for immunoblockade." Ex. 1022, 571. It further states that antibody "clearly diffuses *into the synaptic cleft*." *Id.*; Pet. 45. Teva and its expert Dr. Foord nevertheless argued that antibody would not reach the synaptic cleft. POR, 37; Ex. 2265, ¶¶ 82-91.

Lilly's Reply and Dr. Balthasar's declaration respond to Teva's argument with evidence that, consistent with the statements in Tan 1995, a POSA would have expected longer distribution times and/or higher doses to improve distribution of full-length antibodies to the synaptic cleft. Reply, 10-11; Ex. 1337 ¶¶ 24-34; Ex. 1022, 571; Ex. 1247, 3972. The challenged portions of Lilly's Reply and Dr. Balthasar's declaration detail the errors and shortcomings of Teva's and Dr. Foord's

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