

IN THE 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 IPR2018-01712
Patent 9,884,908 B2

**PATENT OWNER'S MOTION TO STRIKE IMPROPER REPLY
ARGUMENTS AND EVIDENCE**

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I. Introduction

Pursuant to the Board's October 15, 2019 Order, Patent Owner Teva moves to strike the following arguments and evidence from Lilly's Reply:

- Reply arguments on pages 6, 10-11, and 15-16;
- Exhibit 1287; and
- Paragraphs 22, 24-25, and 30-33 of Exhibit 1341.

These are not rebuttal arguments and evidence; rather, they represent Lilly's impermissible attempt to present new evidence and theories of invalidity. "[A] reply that raises a new issue or *belatedly presents evidence may not be considered.*" Trial Practice Guide at 40 (emphasis added). Permitting Lilly to introduce these new arguments and evidence on Reply would prejudice Teva.

Petitioners are required to provide "[a] full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence including material facts," *in the Petition*, in the first instance, not in the Reply. 37 C.F.R. § 42.22(a)(2); *see also Tietex Int'l v. Precision Fabrics Group*, IPR2014-01248, Paper 39 at 14-15 (PTAB Feb. 27, 2016). A Reply is for rebuttal, not to rehabilitate flawed theories in a Petition, as Lilly attempts here by introducing new arguments and evidence—including the declaration of an entirely new expert to proffer the same opinions as its first, and since discredited, expert. 37 C.F.R. § 42.23 ("A reply may only respond to arguments raised in the

corresponding opposition.”); Trial Practice Guide at 40; *see also Henny Penny Corp. v. Frymaster LLC*, No. 2018-1596, slip. op. at *9 (Fed. Cir. Sept. 12, 2019). Because Lilly failed to rely upon these new arguments and evidence in its Petition, Teva respectfully requests that the Board strike them.

II. Lilly improperly puts forth a new theory and evidence related to Exhibit 1287.

Teva’s Response exposed a hole in Lilly’s Petition: Tan 1995 is a basic science pharmacology paper that draws no therapeutic or clinical conclusions. POR, 16. The authors intended simply “to investigate immunoblockade as an alternative strategy for probing the role of CGRP as a vasodilator in vivo.” EX1022, Abstract. Thus, Tan 1995 was trying to elucidate CGRP’s role in vasodilation in an experimental animal; not whether an anti-CGRP antibody could be safely developed for human therapeutic use. EX2267, ¶¶83, 121; EX2270, ¶137.

Facing this hole in its primary case, Lilly improperly puts forth new Exhibit 1287 for the first time on Reply to supplement its deficient motivation argument to humanize the claimed anti-CGRP antagonist antibodies. This exhibit should have been filed with Lilly’s Petition. Exhibit 1287 is an entirely new 275-page dissertation, which was not cited previously, was not relied upon by any of Lilly’s experts, and, importantly, was not even shown to be a publicly-available printed publication prior to November 14, 2005.

Lilly relies on EX1287 in Reply to allege that “there [was] ‘no reason’ why

humanized anti-CGRP antagonist antibodies should not be developed and used for treating migraine.” Reply at 6, citing EX1287, 247; *see also* Reply, 15-16. By citing to this dissertation by Tan, who was a student and not a POSA as of his writing, Lilly aims to insert new evidence necessary to its original invalidity theories. But any arguments and evidence as to motivation must have been made in the Petition, not newly advanced for the first time on Reply. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369-70 (Fed. Cir. 2016) (indicating that a reply or reply evidence may be excluded if it introduces new evidence that is necessary to make out a *prima facie* case of unpatentability). Exhibit 1287 is not used to rebut an argument, but instead to plug a deficiency in Lilly’s original evidence on purported motivation. Lilly has given no reason why it could not have included Exhibit 1287 in its Petition. Permitting Lilly to introduce it now to cure flaws in the Petition would be improper. Thus, the Board should strike Lilly’s Reply arguments relating to Exhibit 1287 (pp. 6 and 15-16) and the entirety of Exhibit 1287.

III. Lilly improperly presents a new expert (Dr. Balthasar) to rehabilitate the discredited testimony of its first expert (Dr. Charles).

In the Petition, Lilly relied on Dr. Charles’s expert testimony to support its allegations regarding the effectiveness of Tan 1995’s full-length antibody.

EX1018, e.g., ¶¶57-60, 78-79, 148-149. This argument was central to Lilly’s *prima facie* obviousness case because Lilly relies on efficacy of Tan’s antibody to argue

motivation to combine. Petition at e.g., 18-19, 25, 27, 30-32, 40-41.

But on cross examination, Dr. Charles was shown to be unqualified to proffer these opinions, and his testimony was discredited. POR, 4. Lilly's other expert, Dr. Vasserot, undermined Dr. Charles' opinions, testifying that certain data in Tan 1995 are "something that [he] would take with caution and would need to repeat." POR, 3, 15-17; EX2191, 118:21- 119:1. Thus, Lilly's Petition Declarants did not support Lilly's Petition arguments. And Teva's experts fully explained that Tan 1995's data does not demonstrate efficacy. EX2267, ¶¶84-85; EX2270, ¶91.

Faced with this vital failure in its Petition, Lilly on Reply seeks to introduce the testimony of a brand new expert, Dr. Balthasar, on the same efficacy issue Dr. Charles failed to support in its Petition. Reply, 10-12; EX1341, ¶¶22, 24-25, 30-33; EX1018, ¶¶57-60. This clearly evidences Lilly's attempt to shore up the same arguments that Lilly relied on in its Petition through new expert testimony on Reply.

Lilly's belated introduction of Dr. Balthasar's declaration to further support its original argument that there was motivation to arrive at the claimed methods based on Exhibit 1022 is impermissible at this stage. Dr. Balthasar's declaration testimony on this point (EX1341, ¶¶22, 24-25, 30-33) and Lilly's arguments based on the same (Reply, 10-11) should be stricken.

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