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 IPR2018-01427
Patent 8,597,649 B2

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

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I. Introduction

Pursuant to the Board's September 20, 2019 Order, Patent Owner Teva moves to strike the following arguments and evidence from Lilly's Reply:

- Reply arguments on pages 3, 9, 11-12, 20;
- Exhibits 1082, 1240, 1287, 1309;
- Paragraphs 15-34, 38, 51, 52, 54, 60, 69 of Exhibit 1329; and
- Paragraphs 17, 31, 74, and 77 of Exhibit 1330.

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). Having 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.

For the first time on Reply, Lilly improperly puts forth new Exhibit 1287 to supplement its motivation to humanize the claimed anti-CGRP antagonist antibodies argument. 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 cites to Exhibit 1287 for motivation in two sections in its Reply. First, in a three-sentence paragraph beginning: "Providing *further* motivation …" as an alleged "contemporaneous" teaching of motivation. Reply at 3, citing EX1287, 247 (emphasis added). Second, to allege that "there was 'no reason' why *humanized* anti-CGRP monoclonal antibodies should not be investigated." Reply at 11, citing EX1287, 247. By citing to this dissertation by Dr. Tan, who was not even a POSA as of his studies, Lilly aims to insert new evidence to bolster 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.

Exhibit 1287 is not used to rebut an argument, but instead to plug a glaring 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. 3, 11-12) 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. EX1002, e.g., ¶¶56-59, 68-71, 115-123. 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., 19-21, 30-32.

But on cross examination, Dr. Charles was shown to be unqualified to proffer these opinions, and his testimony was discredited. POR, 3-4. 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, 16-18; 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. EX2054, ¶52; EX2137, ¶88.

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, 20; EX1329, ¶¶15-34. Remarkably, multiple paragraphs in Dr. Balthasar's declaration on Tan's full-length antibody mirror Dr. Charles's testimony on the same point. *Compare* EX1329, ¶¶16-18, 20, 22, 24-26, 29-30, 32-33 *with* EX1002, ¶¶49-51, 56-57, 70, 121, 126, 131-132, 138, 162. This clearly evidences Lilly's blatant 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 antibodies based on Exhibit 1022 is impermissible at this stage. Dr. Balthasar's declaration testimony on this point (EX1329, ¶¶15-34) and Lilly arguments based on the same (Reply, 20) should be stricken.

IV. Lilly improperly puts forth a new theory and evidence relating to aptamers.

Teva's POR revealed that none of the art in Lilly's Petition demonstrates that a POSA would have considered a long-acting anti-CGRP drug, like the claimed full-length antibody, safe and effective. Unable to find any support to rebut that showing, Lilly on Reply advances new evidence, new expert testimony, and new art involving "aptamers"—oligonucleotides directed to the CGRP ligand—to newly argue that the "prior art demonstrated that longer acting anti-

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