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 IPR2018-01710 (Patent No. 8,586,045)
Case IPR2018-01711 (Patent No. 9,884,907)
Case IPR2018-01712 (Patent No. 9,884,908)[1]

PATENT OWNER'S SURREPLY TO PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE

[1] This paper was authorized by email on January 16, 2019, and is filed in each proceeding identified in the caption. Citations refer to papers filed in IPR2018-01710. Emphases are added unless otherwise noted.

I. Introduction

During prosecution, the Office thoroughly considered substantially the same prior art teachings and arguments in Lilly's Petition, and still found the claimed subject matter patentable. These facts warrant denying institution under § 325(d). Lilly's Reply does not overcome these fatal deficiencies, nor otherwise provide any valid reason for the Board to wastefully redo the examiner's analysis.

A. The examiner reviewed the same prior art teachings and already rejected arguments similar to Lilly's during prosecution

Lilly's unremarkable statement that the examiner did not present an obviousness rejection based on Olesen, Tan, or Queen (Reply, 1) is legally irrelevant because the *teachings* from Lilly's cited references are the same as, or cumulative of, those the examiner considered during prosecution of the challenged patents and raised in rejections during prosecution of related patents. The Board routinely denies institution under § 325(d) when the art is not new or is cumulative, as the art is here. *Cultec Inc. v Stormtech LLC*, IPR2017-00777, Paper 7 (PTAB Aug. 22, 2017); *see also Unified Patents Inc. v. John L. Berman*, IPR2016-01571, Paper 10 (PTAB Dec.14, 2016); *Dorco Co. v. Gillette Co*, IPR2017-00500, Paper 7 (PTAB June 21, 2017); and *Indivior Inc. v. Rhodes Pharms, L.P.*, IPR2018-00795, Paper 23 (PTAB Oct. 4, 2018).

1. Olesen is cumulative of teachings the examiner considered and applied in prosecution

It is irrelevant whether Olesen itself was cited to the office when the same

teachings Lilly relies upon from Olesen are cumulative of teachings that were. Olesen reported results of a clinical trial using the small molecule CGRP-receptor antagonist BIBN4096BS for migraine. *See generally* EX1025. Teva's patent specification explicitly mentions BIBN4096BS's effects on migraine via CGRP involvement: "[p]ossible CGRP involvement in migraine has been the basis for the development and testing of a number of compounds that ... antagonize at the CGRP receptor (e.g., dipeptide derivative BIBN4096BS (Boehringer Ingelheim)." EX1001, 2:14-23. It also provides data relating to Olesen's disclosures, by way of Example 6, which compares the effects of BIBN4096BS to an anti-CGRP antagonist antibody in an *in vivo* ***migraine model***. *Id.*, Example 6 and Figure 9. And the examiner was aware of these data, as seen by Applicant's discussion of Example 6's use of anti-CRGP antagonists in a migraine model when responding to a rejection during the prosecution of the '045 patent. EX2034, 497. Olesen provides nothing new.

Lilly attempts to extend Olesen beyond its small molecule receptor antagonist to anti-CGRP antagonists in general.[2] But, the examiner was also well aware of anti-CGRP antagonists in general through Frobert and Pisegna; the references the examiner used in rejections during prosecution of related patents.

[2] Notably, Lilly supports its characterization of Olesen (and Tan) by quoting its own Petition, rather than Olesen (or Tan). *See* Reply 2 and 4, citing Petition.

Indeed, Lilly acknowledges that Frobert teaches anti-CGRP antibodies (Petition 12) and that Pisegna taught potential therapeutic antibodies that "compete with each other or with other possible ligands to the CGRP-receptors." *Id*., 53. Thus, Olesen is cumulative of the prior art teachings in the specification of the patents and already considered and applied in prosecution.

Tellingly, Olesen's teachings suffer from the same deficiency as Pisegna: they focused on targeting the CGRP *receptor*, not CGRP itself. Olesen does not expressly mention any CGRP antagonists other than a ***receptor antagonist***, a fact that Lilly does not dispute. Indeed, Lilly admits that Olesen's focus is on "BIBN4096BS, a known CGRP-receptor antagonist." Petition, 14. The Board need not expend its resources reviewing these cumulative teachings of Olesen.

2. The examiner expressly considered Tan during prosecution; Lilly fails to show that the examiner erred when doing so

Lilly argues—ineffectively—that Tan is not cumulative to Frobert and Pisegna. *Id.*, 4. Even assuming Lilly is correct—which it is not—its argument is irrelevant because Tan itself was squarely before the Office and discussed during prosecution, as fully explained in the POPR. POPR, 17-20. As Lilly acknowledges, the patents' specification cites Tan for teaching anti-CGRP antibodies (EX1001, 25:59-61) and when describing the rat saphenous nerve assay (*id*., 55:55-58). *See* Petition, 7. Moreover, Applicant expressly highlighted that Tan's rat saphenous nerve assay results provided no motivation to humanize an anti-CGRP antibody in

response to an Office Action. POPR 18-19; EX2005, 182[3]. There can be no dispute: the examiner considered Tan's disclosure of anti-CGRP antagonist murine antibodies and the rat saphenous nerve assay, the key teachings upon which Lilly hangs its challenge[4]. The filed IDS noting the date on which Tan was considered (EX2034, 480) is additional dispositive evidence that Tan was fully considered. Instead of refuting this evidence, Lilly simply disagrees with the examiner's decision to allow Teva's patents; but that does not justify institution. *Apotex Inc. v. Celgene Corp.*, IPR2018-00685, Paper 8, 26 (PTAB Sept. 27, 2018).

Lilly's reliance on *Navistar* (Reply, 5) and *Vizio* (Reply, 3 and 5) is misplaced. Both cases are readily distinguishable. In *Navistar* and *Vizio*, the examiner presented no §§ 102/103 rejections evincing consideration of the prior art teachings. *Navistar Inc. v. Fatigue Fracture Tech., LLC*, IPR2018-00853, Paper 13 at 17; *Vizio Inc. v. Nichia Corp.*, IPR2017-00551, Paper 9 at 8. Here, in contrast,

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[3] In *Microsoft Corp. v. Koninklijke Philips N.V.*, the Board considered references relied upon during prosecution of related patents relevant to its § 325(d) analysis and denied institution. IPR2018-00279, Paper 11, 8-18.

[4] Lilly ignores that the '045 patent's Corrected Notice of Allowance issued the same day as the Notice of Allowance for the '649 patent. Reply FN4; EX2005, 278-280; EX2034, 542-544. The same examiner considered Teva's Tan arguments in the '649 prosecution before allowing the '045 patent.

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