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 IPR2018-01422 (Patent No. 9,340,614)
Case IPR2018-01423 (Patent No. 9,266,951)
Case IPR2018-01424 (Patent No. 9,346,881)
Case IPR2018-01425 (Patent No. 9,890,210)
Case IPR2018-01426 (Patent No. 9,890,211)
Case IPR2018-01427 (Patent No. 8,597,649)[1]

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

[1] This paper is filed in each proceeding identified in the caption. Citations refer to papers filed in IPR2018-01422. 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 states unremarkably that the examiner did not combine the specific *references* cited in the Petition—Tan 1995, Wimalawansa, Queen, and Doods.[2] Reply 1-2. This, however, is legally irrelevant because the *teachings* from Lilly's cited references are the same as, or cumulative of, those the examiner considered. The Board routinely denies institution under § 325(d) for this reason. *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

[2] Lilly admits that Queen's teachings are in the patents' specification, adding nothing material to its arguments. Petition, 7-8; Reply, 4. Lilly does not dispute that the examiner filed an IDS noting the date on which he considered Doods (EX2040, 350), conceding that Doods was already considered during prosecution.

Indivior Inc. v. Rhodes Pharms, L.P., IPR2018-00795, Paper 23 (PTAB Oct. 4, 2018). The Board should deny institution here.

1. Wimalawansa is cumulative of art the examiner considered and applied in prosecution

Lilly asserts that Wimalawansa "advocated for making and using *humanized* anti-CGRP antagonist antibodies for therapeutic purposes." Reply, 2 (emphasis in original). However, the examiner relied on other references—Frobert and Pisegna—for that same proposition, when initially rejecting all claims as obvious. EX2005, 162-64; EX2050, 10. Indeed, Lilly acknowledges that Frobert teaches anti-CGRP antibodies (EX2050, 10-11) and that Pisegna taught that "humanized antibodies are desirable for therapeutic applications," just like Wimalawansa. *Id.*, 11. Notably, Teva even highlighted this exact teaching for the examiner during prosecution. EX2005, 181-182. Tellingly, Wimalawansa suffers from the same deficiency as Pisegna: it focused on targeting CGRP *receptors*, not CGRP itself. EX1096, 568 ("[T]he antagonist must be extremely specific to the CGRP receptors … to avoid potential deleterious side effects caused by blocking other … CGRP receptors."). Lilly is incorrect that Wimalawansa provides a "critical" disclosure missing from the art before the examiner. Instead, Lilly simply seeks to substitute the general, but deficient teaching from one reference with the same general, but deficient teaching in another reference. Wimalawansa is cumulative of the prior art teachings already considered and applied in prosecution.

2. The examiner expressly considered Tan 1995 during prosecution and Lilly does not show that the examiner erred when doing so

Lilly readily admits that a number of Tan's teachings are cumulative to Frobert. Reply, 3. Yet, Lilly argues—ineffectively—that Tan 1995 is not "fully" cumulative to Frobert and Pisegna. *Id.*, 3-4. Even assuming Lilly is correct—which it is not—its argument is irrelevant because Tan 1995 itself was squarely before the Office and discussed during prosecution, as fully explained in the POPR. POPR, 15-17. The patents' specification cites Tan 1995 for teaching anti-CGRP antibodies (EX1001, 25:66-26:1) and when describing the rat saphenous nerve assay (*id*., 55:65-56:1). Moreover, Applicant expressly highlighted that Tan 1995's rat saphenous nerve assay results provided no motivation to humanize an anti-CGRP antibody in response to an Office Action. POPR 16-17; EX2005, 182[3]. Thus, there can be no dispute that the examiner already considered Tan 1995's disclosure of anti-CGRP antagonist antibodies and the rat saphenous nerve assay, the key disclosures upon which Lilly hangs its challenge.

The filed IDS noting the date on which Tan 1995 was considered (EX2040, 362) is additional dispositive evidence that Tan 1995 was fully considered. Instead

[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 at 8-18.

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 at 26 (PTAB Sept. 27, 2018). Lilly's reliance on *Navistar* (Reply 1-2, and 5) and *Vizio* (Reply at 4, 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, the record demonstrates that the examiner considered prior art teachings and addressed arguments the same as, or cumulative to, those presented in the Petition, confirmed by the examiner's rejections and Teva's response thereto. POPR, 15-24. This case is therefore much closer to the facts before the Board in *Microsoft* and *Indivior*, where the Board exercised its discretion to deny institution under § 325(d) given the extensive prosecution before the examiner, the overlapping and cumulative references cited in the petition, and the examiner's signed IDS. *See, e.g., Microsoft*, IPR2018-00279, Paper 11 at 8-18; *Indivior*, IPR2018-00795, Paper 23 at 9.

Finally, Lilly has not demonstrated that the examiner erred when considering Tan 1995. To the contrary, Lilly actually admits that the sections from Tan 1995 presented to the examiner during prosecution "appear to support [a] contention"

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