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 IPR2018-01425
Patent 9,890,210

TEVA PHARMACEUTICALS INTERNATIONAL GMBH'S PRELIMINARY RESPONSE UNDER 37 C.F.R. § 42.107(a)

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

I. Introduction 1

II. CGRP, CGRP receptor antagonists, and the inventors' unorthodox switch to CGRP antagonist antibodies 4

III. The Board should deny institution under 35 U.S.C. § 325(d) because the Petition is based on substantially the same prior art and arguments already considered by the USPTO 10

A. The same examiner reviewed the references or equivalents thereof and rejected Petitioner's arguments during prosecution of the '210 patent and its parent '649 patent 12

B. All of the *Becton Dickinson* factors strongly favor denying institution under § 325(d) 14

1. Each of the primary references—Tan, Wimalawansa, and Queen—is the same or substantially the same as the art that was overcome during examination 15

2. The asserted art was fully evaluated during examination and was the basis for rejection 21

3. The Petition's prior art references are cumulative of the art evaluated during prosecution 21

4. The arguments in the Petition substantially overlap with the examiner's arguments during prosecution 22

5. Lilly offers no explanation for how the examiner erred during prosecution when evaluating the same art 24

6. Lilly provides no justification to reconsider the same art and arguments from prosecution 26

IV. Petitioner failed to establish a reasonable likelihood of prevailing as to any challenged claim 27

A. Claim construction 28

B. Person of ordinary skill in the art 28

C. Lilly should be held to its Tan 1995, Wimalawansa, and Queen obviousness combination 29

D. Lilly does not demonstrate why a POSA would have humanized Tan's full-length antibody 31

1. Lilly fails to provide any reason a POSA would have had to modify Tan 1995's full-length C4.19 antibody by humanization 32

a) Tan 1995 did not establish that C4.19 antagonized endogenous CGRP; a critical prerequisite to Lilly's argument that is missing for motivation 34
b) Lilly fails to address why a POSA would not expect Tan 1995's negative result to also apply to other full-length anti-CGRP antibodies..... 38
2. Wimalawansa provides no reason to humanize Tan 1995's failed full-length C4.19 antibody 42
a) Lilly argues that Wimalawansa would have motivated a POSA to generate humanized anti-CGRP antagonist antibodies for therapeutic use, but Wimalawansa cautions against this approach, focusing on *receptor* antagonists instead 43
b) Lilly does not provide any evidence of the "data from carefully designed studies" that Wimalawansa deemed necessary before a POSA would begin to evaluate anti-CGRP monoclonal antibodies for human use..... 48
E. Lilly's near-simultaneous invention theory is neither supported by the facts nor the law.....52
V. Conclusion 54

Patent Owner Teva Pharmaceuticals International GmbH ("Patent Owner") provides this preliminary response to Petitioner Eli Lilly and Company's ("Lilly") petition for *inter partes* review of claims 1-15 of U.S. Patent No. 9,890,210 ("the '210 patent"; EX1001) in accordance with 37 C.F.R. § 42.107(a).

I. Introduction

In this proceeding, Lilly wants to cancel Teva's patent claims protecting its groundbreaking, humanized monoclonal anti-CGRP antagonist antibodies. Yet Lilly's entire effort to cancel as obvious claims to something that it once itself thought worthy of patenting is troubling. *See* EX1127. Until the present inventors' contribution, the therapeutic focus for CGRP receptor-mediated disorders was on CGRP *receptor* antagonism, and the antagonist development focused on *small molecule receptor* antagonists, such as BIBN4096BS. EX1025. Before the present inventors filed their humanized anti-CGRP antagonist antibody applications, to the extent that antibodies to CGRP were used, it was as research tools to answer basic science questions related to, for example, receptor-ligand interaction. That Lilly now turns to those same research tools as a basis for its obviousness challenge contradicts its own contemporaneous efforts to seek patent protection for anti-CGRP antibodies and methods of use thereof.

To be instituted, an IPR petition must establish a reasonable likelihood that it could prevail against at least one challenged claim. Lilly's Petition fails to meet this

requirement here for multiple separate and independent reasons, any one of which compels denial of institution. This Board routinely exercises its discretion under 35 U.S.C. § 314(a) and 37 C.F.R. § 42.5 to deny institution when it determines, as it should here, that a petitioner fails to demonstrate a reasonable likelihood of prevailing on at least one challenged claim. *See Apple, Inc. v. Contentguard Holdings, Inc.*, IPR2015-00355, Paper 9 at 15-16 (PTAB June 26, 2015).

As a threshold matter, institution should be denied under 35 U.S.C. § 325(d) because Lilly's Petition does no more than attempt to resurrect the same or substantially the same prior art and arguments that were previously before the examiner during prosecution and were overcome. What's more, each of the primary references in the challenged ground were either already squarely before the examiner, or are cumulative to references raised and overcome during prosecution, and the Petition does not sufficiently demonstrate that the examiner somehow erred in evaluating those references. Thus, the Board need not, and indeed should not, waste valuable resources second-guessing the examiner without any adequate justification.

Setting aside that the Board can and should deny institution here under its § 325(d) discretion, Lilly's Petition independently deserves denial because it fails to make the necessary threshold showing of a reasonable likelihood that any challenged claim is unpatentable as obvious over the cited references. Lilly's

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.