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 IPR2018-01423 U.S. Patent No. 9,266,951

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

1.	Introduction							
II.		RP, CGRP receptor antagonists, and the inventors' unorthodox switch to RP antagonist antibodies4						
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							
	A.	thereo	The same examiner reviewed the references or equivalents nereof and rejected Petitioner's arguments during rosecution of the '951 patent and its parent '649 patent					
	B.		All of the Becton Dickinson factors strongly favor denying institution under § 325(d)					
		1.	Each of the primary references—Tan, Wimalawansa, Queen, and Doods—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	22				
		3.	The Petition's prior art references are cumulative of the art evaluated during prosecution	22				
		4.	The arguments in the Petition substantially overlap with the examiner's arguments during prosecution	24				
		5.	Lilly offers no explanation for how the examiner erred during prosecution when evaluating the same art	26				
		6.	Lilly provides no justification to reconsider the same art and arguments from prosecution	28				
IV.	Petitioner failed to establish a reasonable likelihood of prevailing as to a challenged claim							
	A.	Clain	n Construction	30				



В.	Person of ordinary skill in the art						
C.	•	Lilly should be held to its Tan 1995, Wimalawansa, Queen, and Doods obviousness combination					
D.	-		not demonstrate why a POSA would have Tan's full-length antibody	33			
	1.	had t	fails to provide any reason a POSA would have to modify Tan 1995's full-length C4.19 antibody amanization	34			
		a)	Tan 1995 did not establish that C4.19 antagonized endogenous CGRP; a critical prerequisite to Lilly's argument that is missing for motivation	36			
		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	40			
	2.	Wimalawansa provides no reason to humanize Tan 1995's failed full-length C4.19 antibody					
		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	45			
		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	50			
E.			n entirely fails to address motivation to humanize gment of Tan 1995	55			
	1.		Petition omits a reason to humanize a Fab'	56			



Case IPR2018-01423 Patent No. 9.266.951

1 410	110110.	Lilly's evidence submitted with its Petition does not support a reason to humanize a Fab' fragment						58
	F.	-	s near-simultaneous orted by the facts nor the		-			60
V.	Con	clusion.						62



Patent Owner Teva Pharmaceuticals International GmBH ("Teva") provides this preliminary response to Petitioner Eli Lilly and Company's ("Lilly") petition for *inter partes* review of claims 1-6 and 14-19 of U.S. Patent No. 9,266,951 ("the '951 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, a petition for IPR must establish at least a reasonable likelihood that it could prevail against at least one challenged claim. Lilly's Petition



DOCKET

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.

