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 IPR2018-01426
U.S. Patent No. 9,890,211

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

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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. 9,890,211 ("the '211 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

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