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
U.S. Patent No. 8,586,045

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, 3, 4, 8-17, 19, 20, and 24-31 of U.S. Patent No. 8,586,045 ("the '045 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 methods of using humanized monoclonal anti-CGRP antagonist antibodies to treat headache, including migraine[1]. 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 early-stage 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

[1] Claim 1 is directed to treating any vasomotor symptom, and is not specific to migraine. EX1001. However, Lilly's arguments against claim 1 rely on migraine treatment. Petition, 49-50. To the extent that Lilly offers an additional reason as to why a POSA would have been motivated to use an anti-CGRP antagonist antibody "to reduce incidence of or treat skin vasodilation" (Petition, 50), Lilly's argument also fails, for the reasons described below.

their patent 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 methods of using anti-CGRP antibodies to treat migraine. *See* EX1127.

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,

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