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
Patent 8,586,045 B2

TEVA PHARMACEUTICALS INTERNATIONAL GMBH'S PATENT OWNER RESPONSE

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Teva Pharmaceuticals International GmbH timely submits this Patent Owner Response to the Petition for *Inter Partes* Review of U.S. Patent No. 8,586,045 filed by Eli Lilly and Company. Teva's Response is supported by the expert declarations of Drs. Michel Ferrari, Ian Tomlinson, Steven Foord, Alan Rapoport, and Robert Stoner, and fact declaration of Jaume Pons. EX2268, ¶¶4-11; EX2271, ¶¶4-9; EX2265, ¶¶1-13; EX2262, ¶¶4-11; EX2274, ¶¶1-4; EX2331.

I. Introduction

The challenged claims recite novel methods of treating vasomotor symptoms, including migraine, using humanized anti-Calcitonin Gene-Related Peptide ("CGRP") antagonist[1] antibodies. Patent Owner Teva's discovery was a breakthrough, representing the first time that *anyone*, *anywhere* developed a humanized anti-CGRP antibody for human therapeutic use. As a result, the approved use of Teva's Ajovy® (fremanezumab-vfrm)—a commercial embodiment of the challenged patent claims—was the ***first and only*** approved use of an anti-CGRP drug for treating migraine.[2] Confronted with the pioneering nature of Teva's invention, Lilly resorts to hindsight to build its faulty obviousness case.

[1] Antagonism is inhibition of a physiological function. EX2265, ¶24.

[2] Ajovy® is indicated for the preventive treatment of migraine. EX2168, 1.

In deciding to institute trial, the Board accepted Lilly's allegations that a skilled artisan ("POSA"[3]) would have been motivated to treat migraine using a humanized anti-CGRP antibody based on Olesen's data related to a small-molecule CGRP receptor antagonist, BIBN4096BS, and Tan—a basic laboratory research paper attempting to "prob[e] the role of CGRP as an endogenous vasodilator" in rats. EX1022, Abstract. But institution was based on a limited record reflecting Lilly's one-sided rendition of the facts. As shown in this Response, Lilly's arguments suffer from multiple flaws and missing steps that defeat its obviousness case. Upon consideration of the full record, the Board should find that substantial evidence exists to revisit and reverse its preliminary determination, which was based on a limited record. *See Apotex Inc. et. al. v. Novartis AG*, IPR2017-00854, Paper 109, 19, 23-24 (PTAB July 11, 2018). The full record demonstrates that a POSA in November 2005 would not have viewed an anti-CGRP antibody as sufficiently safe or effective for reducing incidence of or treating migraine.

Lilly cherry-picks aspects of the art, ignoring important uncertainties and complexities in the field that negate obviousness. Lilly starts by arguing that CGRP was proven to be involved in migraine, citing Goadsby's papers (EX1043, EX1044), while ignoring contradictory data that arose after Goadsby and before

[3] Teva adopts the Board's definition of a POSA. *See* Decision, 7-9.

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