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
Patent 9,890,211 B2

TEVA PHARMACEUTICALS INTERNATIONAL GMBH'S PATENT OWNER RESPONSE

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Teva Pharmaceuticals International GmbH ("Teva") submits this Patent Owner Response to the Petition for *Inter Partes* Review ("IPR") of U.S. Patent No. 9,890,211 filed by Eli Lilly and Company ("Lilly"). Teva's Response is supported by the expert declarations of Michel Ferrari, Ian Tomlinson, Steven Foord, Alan Rapoport, and Robert Stoner. EX2214, ¶¶4-11; EX2226, ¶¶4-9; EX2232, ¶¶4-13; EX2237, ¶¶4-11; EX2243, ¶¶1-4. This filing is timely under 35 U.S.C. §§ 311-19 and 37 C.F.R. § 42.120.

I. Introduction

The challenged claims recite novel *humanized* anti-Calcitonin Gene-Related Peptide ("CGRP") antagonist[1] antibodies useful in the treatment of various vasomotor-related ailments, including migraine. Patent Owner Teva's discovery was a breakthrough, representing the first time that *anyone, anywhere* in the world developed a humanized anti-CGRP antibody that could successfully be used as a human therapeutic. As a result, Teva's Ajovy® (fremanezumab-vfrm)—the first commercial embodiment of the challenged patent claims—when approved, was the

[1] Antagonism is achieved when a molecular blocker inhibits receptor signaling. EX2232, ¶21.

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