IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

)
TEVA PHARMACEUTICALS) Case No. 1:18-cv-12029-ADB
INTERNATIONAL GMBH and	
TEVA PHARMACEUTICALS USA, INC.,)
Plaintiffs,)
) Leave to File Granted on
v.) Feb. 22, 2022 (ECF No. 272)
ELI LILLY AND COMPANY,) Leave to File Under Seal Granted or
EBI BEBI THOS COMPTICE,) Mar. 28, 2022 (ECF No. 285)
Defendant.)

DEFENDANT ELI LILLY AND COMPANY'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT OF NO WILLFUL INFRINGEMENT



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I. INTRODUCTION

Teva's patent infringement assertions against Lilly's Emgality® (galcanezumab) antibody therapy for treatment of migraine and episodic cluster headache have evolved over the last four and a half years. After two false start complaints that this Court dismissed for lack of subject matter jurisdiction, and after six of the nine patents initially asserted in Teva's operative complaint were invalidated by the Patent Trial and Appeal Board ("PTAB"), only three method of treatment patents remain in this case (the "patents-in-suit"). But what has not evolved over the years are Teva's allegations of willful infringement. Consisting of the same language and form as the day they were filed, Teva's willfulness claims constitute little more than boilerplate legal conclusions even after fact and expert discovery have closed. The Federal Circuit has clarified twice since this litigation began that a proper willfulness inquiry revolves around the infringer's subjective beliefs and specific intent to infringe a valid patent. Even as the law of willfulness itself has evolved, Teva has never amended or supplemented its pleadings to keep up with the law and to carry its burden of proof.

A review of the facts of record in this case shows that there are no genuine factual disputes for a jury to resolve regarding willfulness. Teva has not alleged "pre-suit" willful infringement. Indeed, the facts demonstrate that before the earliest patent-in-suit here was filed (July 11, 2011), and Lilly began clinical trials before Teva. Teva's patents had no impact whatsoever on Lilly's independent research and development of an anti-CGRP antibody for preventive treatment of migraine and episodic cluster headache. At most, the existence of the single full-length humanized antibody disclosed in the patents-in-suit ("Antibody G1") served to confirm how significantly *different* Lilly's antibody was from Antibody G1. As for "post-suit" willfulness, which many courts have concluded does not exist as a legal doctrine (*see infra* §IV.A), Lilly is merely selling an accused product, Emgality®,



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