### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS INTERNATIONAL GMBH and TEVA PHARMACEUTICALS USA, INC.,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

Civil Action No. 1:18-cv-12029-ADB



### PLAINTIFFS' MEMORANDUM IN SUPPORT OF THE MOTION TO EXCLUDE CERTAIN OPINIONS OF DEFENDANT'S EXPERT JAMES M. MCDONNELL, PH.D.

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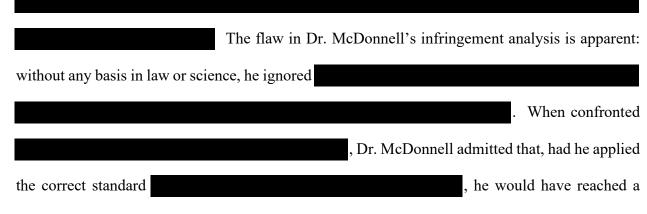
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#### I. INTRODUCTION

James M. McDonnell, Ph.D., an expert witness for defendant Eli Lilly and Company ("Lilly"), has proffered opinions in his expert reports in support of Lilly's written description, enablement, and inequitable conduct defenses. He has also given opinions in support of Lilly's argument that use of its Emgality® product does not infringe the asserted claims. The Court should exercise its gatekeeping function to exclude two aspects of Dr. McDonnell's testimony.<sup>1</sup>

First, Dr. McDonnell's opinion that the use of Lilly's Emgality<sup>®</sup> product does not literally infringe the asserted claims is based on an incorrect understanding of the law. The question of infringement requires an expert (and ultimately the fact finder) to compare the properties and characteristics of the accused product (here, Lilly's Emgality®) to the limitations of the asserted claims. Dr. McDonnell opined that Lilly does not infringe the asserted claims because galcanezumab, the active ingredient in Emgality<sup>®</sup>, is not a "humanized antibody" as that term has been construed by the Court. To reach this conclusion, Dr. McDonnell ignored available evidence that speaks directly to the characteristics of Emgality<sup>®</sup>—



different conclusion. Opinions that are based on a misunderstanding of the law and that ignore

<sup>&</sup>lt;sup>1</sup>Below, Teva identifies several paragraphs in Dr. McDonnell's reports that contain these improper opinions. To the extent such opinions appear elsewhere in Dr. McDonnell's report, those opinions should be excluded for the same reasons.

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