

**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

[REDACTED]

[REDACTED]

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

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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.¹

First, Dr. McDonnell’s opinion that the use of Lilly’s Emgality® 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®, 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®— [REDACTED]

[REDACTED] The flaw in Dr. McDonnell’s infringement analysis is apparent: without any basis in law or science, he ignored [REDACTED]. When confronted [REDACTED], Dr. McDonnell admitted that, had he applied the correct standard [REDACTED], he would have reached a different conclusion. Opinions that are based on a misunderstanding of the law and that ignore

¹ 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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