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]

PLAINTIFFS TEVA PHARMACEUTICALS INTERNATIONAL GMBH AND TEVA PHARMACEUTICALS USA, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT REGARDING INEQUITABLE CONDUCT AND UNCLEAN HANDS

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I. INTRODUCTION

Federal Circuit precedent has significantly limited the doctrine of inequitable conduct, ensuring that the "'atomic bomb' of patent law" can only be used in truly "egregious circumstances." *Therasense, Inc. v. Benton, Dickinson & Co.*, 649 F.3d 1279, 1288 (Fed. Cir. 2011) (en banc); *Lexington Luminance LLC v. Osram Sylvania Inc.*, 972 F. Supp. 2d 88, 91 (D. Mass. 2013). Under this "dramatic[ally] constrict[ed]" version of the doctrine, a patent infringer can only avoid the consequences of its wrongful conduct if it can identify clear and convincing evidence that satisfies heightened versions of both the doctrine's materiality and intent elements. *Metris U.S.A., Inc. v. Faro Techs., Inc.*, 882 F. Supp. 2d 160, 166 (D. Mass. 2011). Making those showings has proven exceptionally difficult: In just the three years following *Therasense*, the Federal Circuit precedent limiting the doctrine more than halved the percentage of adequately-pleaded inequitable conduct claims that ultimately succeed—from nearly a quarter to under ten percent. Robert D. Swanson, *The Exergen & Therasense Effects*, 66 Stan. L. Rev. 695, 696 (2014).

Lilly has failed to adduce evidence sufficient to permit a finding, by clear and convincing evidence, that Lilly satisfied *either* the materiality or the intent element—let alone both. Lilly's primary inequitable conduct claim is that [redacted] of the patents-in-suit (Plaintiffs' Statement of Undisputed Material Facts ("SUMF") ¶¶ 1–7)—[redacted]—should have but did not disclose to the PTO one prior art reference ("Shaw") [redacted]. Second Supplemental Amended Answer, Dkt. No. 277 ("SSAA"), Count XXI; SUMF ¶¶ 13-14. But there is no evidence that this information was even material, let alone that [redacted] affirmatively withheld it from the PTO with the intent to deceive. As to materiality, Lilly offers no testimony that the evidence was material under the *Therasense* standard, which requires a showing that the PTO "would not have allowed a claim" had the information been disclosed, and therefore there is no dispute of fact as to this element. 649

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