

**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.)

Case No. 1:18-cv-12029-ADB

Leave to File Under Seal Granted on
May 6, 2022 (ECF No. 341)

**DEFENDANT ELI LILLY AND COMPANY'S RESPONSE TO PLAINTIFFS'
LR 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT OF NO
INEQUITABLE CONDUCT AND UNCLEAN HANDS**

TABLE OF ABBREVIATIONS

Abbreviation	Description
'045 patent	Patent-in-suit. U.S. Patent No. 8,586,045 to Joerg Zeller et al., issued November 19, 2013, entitled "Methods of Using Anti-CGRP Antagonist Antibodies"; currently assigned to Teva Pharmaceuticals International GmbH
'394 application	U.S. Patent Application No. 13/835,394 to Joerg Zeller et al., filed March 14, 2013, entitled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide and Methods Using Same"; abandoned January 9, 2014
'623 provisional application	U.S. Provisional Patent Application No. 60/736,623, filed November 14, 2005
'816 application	U.S. Patent Application No. 14/086,816 to Joerg Zeller et al., filed November 21, 2013, entitled "Methods of Treating Vasomotor Symptoms Using Antibodies"; issued as U.S. Patent No. 8,734,802 on May 27, 2014
'871 application	U.S. Patent Application No. 13/870,871 to Joerg Zeller et al., filed April 25, 2013, entitled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide and Methods Using Same"; issued as U.S. Patent No. 8,597,649 on December 3, 2013
'907 patent	Patent-in-suit. U.S. Patent No. 9,884,907 to Joerg Zeller et al., issued February 6, 2018, entitled "Methods for Treating Headache Using Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide"; currently assigned to Teva Pharmaceuticals International GmbH
'908 patent	Patent-in-suit. U.S. Patent No. 9,884,908 to Joerg Zeller et al., issued February 6, 2018, entitled "Methods for Treating Headache Using Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide"; currently assigned to Teva Pharmaceuticals International GmbH
'925 application	U.S. Patent Application No. 14/251,925 to Joerg Zeller et al., filed April 14, 2014, entitled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide and Methods Using Same"; issued as U.S. Patent No. 9,115,194 on August 25, 2015
App'x	Appendix
BBB	blood-brain barrier
Blake Tr.	Transcript of deposition of expert Pamela Blake, M.D., FAHS, on behalf of Teva, dated January 10, 2022
Blumenfeld Resp.	Responsive Expert Report of Andrew Blumenfeld, M.D. Regarding Validity, on behalf of Teva, served November 1, 2021
<i>Bold and italicized</i>	emphasis added unless indicated otherwise
Br.	Plaintiffs Teva Pharmaceuticals International GmbH And Teva

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	Pharmaceuticals USA, Inc.'s Memorandum of Law in Support of Motion for Summary Judgment Regarding Inequitable Conduct and Unclean Hands (ECF No. 302); filed March 28, 2022
C.F.R.	Code of Federal Regulations
CGRP	calcitonin gene-related peptide
Charles Declaration	Declaration of Dr. Andrew Charles, in Support of Defendant Eli Lilly and Company's Opposition to Plaintiffs' Motion for Summary Judgment of No Inequitable Conduct and Unclean Hands, filed concurrently
Charles Op. ¹	Opening Expert Report of Dr. Andrew Charles Regarding Invalidity of U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908, on behalf of Lilly, served September 16, 2021
Charles Reply ²	Reply Expert Report of Dr. Andrew Charles Regarding Invalidity of U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908, on behalf of Lilly, served December 7, 2021
Charles Tr.	Transcript of deposition of expert Dr. Andrew Charles, defended by Lilly counsel, dated January 27, 2022
CSD	cortical spreading depression
ECF No.	Documents from the public docket filed through the CM/ECF system. Unless otherwise noted, citations are to the public docket of Case No. 1:18-cv-12029-ADB, D. Mass.
Ex. __	Exhibits to concurrently-filed Declaration of Emily Gabranski in Support of Defendant Eli Lilly and Company's Opposition to Plaintiffs' Motion for Summary Judgment of No Inequitable Conduct and Unclean Hands
Gabranski Declaration	Declaration of Emily Gabranski in Support of Defendant Eli Lilly and Company's Opposition to Plaintiffs' Motion for Summary Judgment of No Inequitable Conduct and Unclean Hands, filed concurrently
Giering Tr.	Transcript of deposition of fact witness Jeffery C. Giering, defended by Teva counsel, dated June 4, 2021.
Hale Resp.	Responsive Expert Report of Geoffrey Hale, Ph.D., Regarding Validity, on behalf of Teva, served November 1, 2021
Hale Tr.	Transcript of deposition of expert Geoffrey Hale, Ph.D., on behalf of Teva, dated January 25, 2022
Hill Reb.	Rebuttal Expert Report of Raymond Hill, Ph.D., Regarding Validity of U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908, on behalf of Teva, served November 1, 2021
McDonnell	Eli Lilly and Company's Memorandum in Opposition to Plaintiffs'

¹ An excerpted copy of Charles Op. is included as Ex. A to the Gabranski Declaration. A full, unexcerpted copy is attached as Exhibit A to the Charles Declaration.

² An excerpted copy of Charles Reply is included as Ex. V to the Gabranski Declaration. A full, unexcerpted copy is attached as Exhibit B to the Charles Declaration.

Daubert Opp.	Motion to Exclude Certain Opinions of James M. McDonnell, Ph.D., filed under seal on May 10, 2022
McDonnell Declaration	Declaration of James M. McDonnell, Ph.D., in Support of Defendant Eli Lilly and Company's Opposition to Plaintiffs' Motion for Summary Judgment of No Inequitable Conduct and Unclean Hands, filed concurrently
McDonnell Op. ³	Opening Expert Report of James M. McDonnell, Ph.D., Regarding Invalidity of U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908, on behalf of Lilly, served September 16, 2021
McDonnell Reply ⁴	Reply Expert Report of James M. McDonnell, Ph.D., Regarding Invalidity of U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908, on behalf of Lilly, served December 7, 2021
McDonnell Tr.	Transcript of deposition of expert James M. McDonnell, Ph.D., on behalf of Teva, dated January 7, 2022
MPEP	Manual of Patent Examining Procedure
Pons Tr.	Transcript of deposition of Jaume Pons, Ph.D., named inventor of the patents-in-suit, dated August 20, 2021
POSA	person of ordinary skill in the art
Poulsen Tr.	Transcript of deposition of Kristian T. Poulsen, named inventor of the patents-in-suit, dated August 5, 2021
PTAB	Patent Trial and Appeal Board of the U.S. Patent and Trademark Office
PTO	U.S. Patent and Trademark Office
RFA	Request for Admission
Rosenthal Tr.	Transcript of deposition of Arnon Rosenthal, Ph.D., named inventor of the patents-in-suit, dated July 30, 2021
RRC	Research Review Committee, Rinat
RSUMF	Citation to paragraph number(s) of Lilly's Responsive Local Rule 56.1 Statement of Material Facts, served May 10, 2022
Shaw	Shaw et al., <i>The effect of monoclonal antibodies to calcitonin gene-related peptide (CGRP) on CGRP-induced vasodilatation in pig coronary artery rings</i> , 106 BR. J. PHARMACOL. 196-98 (1992)
SOF	Citation to paragraph number(s) of one of Lilly's Local Rule 56.1 Statement of Facts, served March 28, 2022
SSAA	Lilly's Supplemental Second Amended Answer and Affirmative Defenses To Plaintiffs' Complaint (ECF No. 275), filed February 24, 2022

³ An excerpted copy of McDonnell Op. is included as Ex. B to the Gabranski Declaration. A full, unexcerpted copy is attached as Exhibit A to the McDonnell Declaration.

⁴ An excerpted copy of McDonnell Reply is included as Ex. H to the Gabranski Declaration. A full, unexcerpted copy is attached as Exhibit B to the McDonnell Declaration.

SUMF	Citation to paragraph number(s) of Teva's Local Rule 56.1 Statement of Material Facts, served March 28, 2022
Teva	Plaintiffs Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc.
U.S.C.	United States Code
USPTO	United States Patent and Trademark Office
WSGR	Wilson Sonsini Goodrich & Rosati

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