IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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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 Granted on Feb. 22, 2022 (ECF No. 272)

Leave to File Under Seal Granted on Mar. 28, 2022 (ECF No 285)

L.R. 56.1 STATEMENT OF MATERIAL FACTS IN SUPPORT OF DEFENDANT ELI LILLY AND COMPANY'S MOTION FOR SUMMARY JUDGMENT OF INVALIDITY FOR LACK OF ENABLEMENT

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TABLE OF ABBREVIATIONS

Short Cite	Description & Other Names/References
'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
'210 patent	U.S. Patent No. 9,890,210 to Joerg Zeller et al., issued February 13, 2018,
	entitled "Antagonist Antibodies Directed Against Calcitonin Gene-
	Related Peptide" currently assigned to Teva Pharmaceuticals International
	GmbH
'211 patent	U.S. Patent No. 9,890,211 to Joerg Zeller et al., issued February 13, 2018,
•	entitled "Antagonist Antibodies Directed Against Calcitonin Gene-
	Related Peptide" currently assigned to Teva Pharmaceuticals International
	GmbH
'614 patent	U.S. Patent No. 9,340,614 to Joerg Zeller et al., issued May 17, 2016,
-	entitled "Antagonist Antibodies Directed Against Calcitonin Gene-
	Related Peptide and Methods Using Same" currently assigned to Teva
	Pharmaceuticals International GmbH
'649 patent	U.S. Patent No. 8,597,649 to Joerg Zeller et al., issued December 3, 2013,
1	entitled "Antagonist Antibodies Directed Against Calcitonin Gene-
	Related Peptide and Methods Using Same" currently assigned to Teva
	Pharmaceuticals International GmbH
'881 patent	U.S. Patent No. 9,346,881 to Joerg Zeller et al., issued May 24, 2016,
Parent	entitled "Antagonist Antibodies Directed Against Calcitonin Gene-
	Related Peptide and Methods Using Same" currently assigned to Teva
	Pharmaceuticals International GmbH
'907 patent	Patent-in-suit. U.S. Patent No. 9,884,907 to Joerg Zeller et al., issued
1	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
500 patent	February 6, 2018, entitled "Methods for Treating Headache Using
	Antagonist Antibodies Directed Against Calcitonin Gene-Related
	Peptide" currently assigned to Teva Pharmaceuticals International GmbH
'951 patent	U.S. Patent No. 9,266,951 to Joerg Zeller et al., issued February 23, 2016,
	entitled "Antagonist Antibodies Directed Against Calcitonin Gene-
	Related Peptide and Methods Using Same" currently assigned to Teva
	Pharmaceuticals International GmbH
Abdiche Tr.	Transcript of deposition of Yasmina Noubia Abdiche, named inventor of
	the patents-in-suit, dated August 17, 2021
BBB	Blood-brain barrier

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DOCKET

Berkman Op.	Expert Report of Mark P. Berkman, on behalf of Teva, served September 16, 2021
Bigal Tr.	Transcript of deposition of fact witness Marcelo Eduardo Bigal, defended by Teva counsel, dated June 10, 2021
Blake Op.	Opening Expert Report of Pamela Blake, M.D., FAHS, Regarding Infringement, on behalf of Teva, served September 16, 2021
Blake Reply	Reply Expert Report of Pamela Blake, M.D., FAHS, Regarding Infringement, on behalf of Teva, served December 7, 2021
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
Blumenfeld Tr.	Transcript of deposition of expert Andrew Blumenfeld, M.D., on behalf of Teva, dated January 26, 2022
CGRP	Calcitonin Gene-Related Peptide
Charles Op.	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 Reb.	Rebuttal Expert Report of Dr. Andrew Charles Regarding Noninfringement, on behalf of Lilly, served November 1, 2021
Charles Reply	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
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 Attorney Declaration
FDA	Food and Drug Administration
Ferrari Decl.	Declaration of expert Dr. Michel D. Ferrari, M.D., Ph.D. on behalf of Teva, filed July 3, 2019 in IPR2018-01710, <i>Eli Lilly & Co. v. Teva</i> <i>Pharms. Int'l GmbH</i>
Foord Decl.	Declaration of expert Steven M. Foord, Ph.D., on behalf of Teva, filed July 3, 2019 in IPR2018-01710, <i>Eli Lilly & Co. v. Teva Pharms. Int'l</i> <i>GmbH</i>
Foord Tr.	Transcript of deposition of expert Steven M. Foord, Ph.D., on behalf of Teva, dated September 27, 2019
FWD	Final Written Decision in an <i>Inter Partes</i> Review proceeding before the United States Patent and Trademark Office Patent Trial and Appeal Board
Hale Resp.	Responsive Expert Report of Geoffrey Hale, Ph.D., Regarding Validity, on behalf of Teva, served November 1, 2021
Hale Supp.	Supplemental Responsive Expert Report of Geoffrey Hale, Ph.D., Regarding Validity, on behalf of Teva, served January 7, 2022
Hale Tr.	Transcript of deposition of expert Geoffrey Hale, Ph.D., on behalf of Teva, dated January 25, 2022

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Harnish Tr.	Transcript of deposition of fact witness Douglas Harnish, Ph.D., defended
	by Teva counsel, dated July 29, 2021
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
Hill Tr.	Transcript of deposition of expert Dr. Raymond Hill, on behalf of Teva,
	dated January 20, 2022
ICHD-II	International Classification of Headache Disorders, 2nd edition
IPR	Inter partes review proceedings at the United States Patent and
II K	Trademark Office
IPR2018-1710	Declaration of expert Dr. Alain P. Vasserot, Ph.D., on behalf of Lilly,
Vasserot Decl.	dated September 9, 2018 in IPR2018-01710, <i>Eli Lilly & Co. v. Teva</i>
vasserot Deer.	Pharms. Int'l GmbH
IPR2018-1711	Declaration of expert Dr. Alain P. Vasserot, Ph.D., on behalf of Lilly,
Vasserot Decl.	dated September 27, 2018 in IPR2018-01711, <i>Eli Lilly & Co. v. Teva</i>
vasserot Deer.	Pharms. Int'l GmbH
IPR2018-1712	Declaration of expert Dr. Alain P. Vasserot, Ph.D., on behalf of Lilly,
Vasserot Decl.	dated September 27, 2018 in IPR2018-01712, <i>Eli Lilly & Co. v. Teva</i>
Vasserot Deer.	Pharms. Int'l GmbH
L.R.	Local Rule
McDonnell Op.	Opening Expert Report of James M. McDonnell, Ph.D., Regarding
MeDonnen Op.	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 Reb.	Rebuttal Expert Report of James M. McDonnell, Ph.D., Regarding
McDonnen Reo.	Noninfringement of U.S. Patent Nos. 8,586,045, 9,884,907, and
	9,884,908, on behalf of Lilly, served November 1, 2021
McDonnell Reply	Reply Expert Report of James M. McDonnell, Ph.D., Regarding Invalidity
MeDonnen Kepty	of U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908, on behalf of
	Lilly, served December 7, 2021
McDonnell Supp.	Supplemental Reply Expert Report of James M. McDonnell, Ph.D.,
MeDonnen Supp.	Regarding Invalidity of U.S. Patent Nos. 8,586,045, 9,884,907, and
	9,884,908, on behalf of Lilly, served January 21, 2022
	9,884,908, on behan of Liny, served January 21, 2022
Mould Op.	Opening Expert Report of Diane R. Mould, Ph.D., FCP, FAAPS, on
Mould Op.	behalf of Lilly, served September 16, 2021
Mould Reply	Reply Expert Report of Diane R. Mould, Ph.D., on behalf of Lilly, served
Would Keply	December 7, 2021
Pons Decl.	Declaration of Jaume Pons, Ph.D., named inventor of the patents-in-suit,
Folis Deci.	on behalf of Teva, filed July 3, 2019 in IPR2018-01710, <i>Eli Lilly & Co. v.</i>
	Teva Pharms. Int'l GmbH
Pons Tr.	Transcript of deposition of Jaume Pons, Ph.D., named inventor of the
10115 11.	patents-in-suit, dated August 20, 2021
DOD	
POR	Patent Owner Response in an <i>Inter Partes</i> Review proceeding before the
DOCA	United States Patent and Trademark Office Patent Trial and Appeal Board
POSA	Person of ordinary skill in the art

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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 United States Patent and Trademark
	Office
Rainey Tr.	Transcript of deposition of fact witness Thomas Edwin Rainey, defended
	by Teva counsel, dated August 10, 2021
Rapoport Tr.	Transcript of deposition of expert Alan M. Rapoport, M.D., on behalf of
	Teva, dated August 22, 2019
Ravetch CC Decl.	Expert Declaration of Jeffrey V. Ravetch, M.D., Ph.D. (ECF No. 70), on
	behalf of Teva, filed September 11, 2020
Ravetch CC Tr.	Transcript of deposition of expert Jeffrey V. Ravetch, M.D., Ph.D., on
	behalf of Teva, dated September 30, 2020
Ravetch	Declaration of Dr. Jeffrey V. Ravetch in Support of Petition for Post
Declaration	Grant Review of U.S. Patent Number 10,611,836 filed January 7, 2021 in
	PGR2021-00036, Merck Sharp & Dohme Corp. v. Genentech, Inc.
Ravetch Op.	Opening Expert Report of Jeffrey V. Ravetch, M.D., Ph.D., Regarding
	Infringement, on behalf of Teva, served September 16, 2021
Ravetch Reply	Reply Expert Report of Jeffrey V. Ravetch, M.D., Ph.D., Regarding
	Infringement, on behalf of Teva, served December 7, 2021
RFA	Request for Admission
Stratton Tr.	Transcript of deposition of fact witness Jennifer Renee Stratton, Ph.D.,
	defended by Teva counsel, dated June 29, 2021
Tomlinson Decl.	Declaration of expert Dr. Ian M. Tomlinson, M.A., Ph.D., on behalf of
	Teva, filed July 3, 2019 in IPR2018-01710, Eli Lilly & Co. v. Teva
	Pharms. Int'l GmbH
Tomlinson Tr.	Transcript of deposition of expert Ian M. Tomlinson, M.A., Ph.D., on
	behalf of Teva, dated August 7, 2019
USPTO	United States Patent and Trademark Office
Walter Tr.	Transcript of deposition of fact witness Sarah Walter, Ph.D., defended by
	Teva counsel, dated June 4, 2021
Zeller Tr.	Transcript of deposition of Jöerg Zeller, named inventor of the patents-in-
	suit, dated August 11, 2021

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