

**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



**FILED UNDER SEAL
LEAVE TO FILE GRANTED
05/06/2022 (ECF NO. 340)**

**LEAVE TO FILE EXCESS
PAGES GRANTED 02/22/2022
(ECF NO. 272)**

**PLAINTIFFS' OPPOSITION TO ELI LILLY AND COMPANY'S MOTION FOR
SUMMARY JUDGMENT OF INVALIDITY FOR LACK OF ENABLEMENT**



TABLE OF CONTENTS

I. INTRODUCTION 1

II. FACTUAL BACKGROUND..... 3

 A. The Person of Ordinary Skill in the Art..... 3

 B. Making Humanized Anti-CGRP Antagonist Antibodies Was Predictable and Routine..... 3

 C. CGRP Was Well-Characterized and Tied to Most Headaches that Required Treatment. 6

III. LEGAL STANDARD..... 7

 A. Summary Judgment 7

 B. Enablement 8

IV. ARGUMENT 10

 A. Lilly’s Motion Papers Violate Local Rule 56.1..... 11

 B. The Court Should Reject Lilly’s Argument that the Patents Do Not Enable the “Claimed Antibodies.” 13

 1. The patents claim *methods* of using human and humanized anti-CGRP antagonist antibodies to treat headache, not the *antibodies themselves*..... 14

 2. Lilly has not established that it would require undue experimentation to make and use the “full scope” of the claimed methods..... 19

 3. Making the claimed antibodies was routine and predictable. 21

 C. Using Humanized Anti-CGRP Antagonist Antibodies to Treat Headache Does Not Require Undue Experimentation..... 24

 1. The vast majority of “headaches” encountered in clinical practice are associated with CGRP..... 24

 2. Testing in humans is not required for Teva’s claims to be enabled. 26

 D. Lilly Has Not Satisfied Its Burden of Proof With Respect to Dependent Claims or the Claims of the ’907 and ’908 Patents. 29

V. CONCLUSION..... 30

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In re '318 Patent Infringement Litig.</i> , 583 F.3d 1317 (Fed. Cir. 2009).....	18, 26
2018 WL 3586271, at *6–*7 (D.N.J. July 26, 2018).....	15
<i>Abbott Biotechnology Ltd. v. Centocor Ortho Biotech, Inc.</i> , 35 F. Supp. 3d 163 (D. Mass. 2014).....	21
<i>Alcon Research Ltd. v. Barr Lab'ys, Inc.</i> , 745 F.3d 1180 (Fed. Cir. 2014).....	21
<i>Allergan, Inc. v. Sandoz Inc.</i> , 796 F.3d 1293 (Fed. Cir. 2015).....	23, 26
<i>Alsina-Ortiz v. Laboy</i> , 400 F.3d 77 (1st Cir. 2005).....	12
<i>Amgen Inc. v. Hoechst Marion Roussel, Inc.</i> , 314 F.3d 1313 (Fed. Cir. 2003).....	9, 13, 28
<i>Amgen Inc. v. Sanofi</i> , 872 F.3d 1367 (Fed. Cir. 2017).....	16
<i>Amgen Inc. v. Sanofi, Aventisub LLC</i> , 987 F.3d 1080 (Fed. Cir. 2021).....	15, 16, 19
<i>Anderson v. Liberty Lobby, Inc.</i> , 477 U.S. 242 (1986).....	7, 8
<i>Baxalta Inc. v. Genentech, Inc.</i> , 2022 WL 420479 (D. Del. Jan. 13, 2022).....	15, 16
<i>In re Biogen '755 Patent Litig.</i> , 335 F. Supp. 3d 688 (D.N.J. 2018).....	14
<i>In re Brana</i> , 51 F.3d 1560 (Fed. Cir. 1995).....	27
<i>Brown v. Armstrong</i> , 957 F. Supp. 1293 (D. Mass. 1997), <i>aff'd</i> , 129 F.3d 1252 (1st Cir. 1997).....	12



Camona v. Toledo,
215 F.3d 124 (1st Cir. 2000).....13

Cephalon, Inc. v. Watson Pharms., Inc.,
707 F.3d 1330 (Fed. Cir. 2013).....9

CFMT, Inc. v. Yieldup Intern. Corp.,
349 F.3d 1333 (Fed Cir. 2003).....13, 18, 23

Chiron Corp. v. Genentech, Inc.,
363 F.3d 1247 (Fed. Cir. 2004).....13

CMI Capital Market Inv., LLC v. González-Toro,
520 F.3d 58 (1st Cir. 2008).....12

In re Depomed Pat. Litig.,
2016 WL 7163647 (D.N.J. Sept. 30, 2016), *aff'd*, 919 F.3d 1333 (Fed. Cir.
2019).....19

Edwards Lifesciences AG v. CoreValve, Inc.,
699 F.3d 1305 (Fed. Cir. 2012).....2, 3, 27

Eli Lilly & Co. v. Actavis Elizabeth LLC,
435 F. App'x 917 (Fed. Cir. 2011).....28, 29

Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.,
276 F. Supp. 3d 629 (E.D. Tex. 2017), *aff'd*, 739 F. App'x 643 (Fed. Cir.
2018)..... *passim*

Falko-Gunter Falkner v. Inglis,
448 F.3d 1357 (Fed. Cir. 2006).....9

Feliciano v. Rhode Island,
160 F.3d 780 (1st Cir. 1998).....8, 12

Geneva Pharms., Inc. v. GlaxoSmithKline PLC,
349 F.3d 1373 (2003).....26

Idenix Pharms. LLC v. Gilead Scis. Inc.,
941 F.3d 1149 (Fed. Cir. 2019).....17, 18, 21

Invitrogen Corp. v. Clontech Labs., Inc.,
429 F.3d 1052 (Fed. Cir. 2005).....8, 29

Johns Hopkins Univ. v. CellPro, Inc.,
152 F.3d 1342 (Fed. Cir. 1998).....8

<i>Kirk v. Raymark Indus., Inc.</i> , 61 F.3d 147 (3d Cir. 1995).....	13
<i>McRO, Inc. v. Bandai Namco Games Am. Inc.</i> , 959 F.3d 1091 (Fed. Cir. 2020).....	29
<i>Merck Sharp & Dohme Corp. v. Genentech</i> , PGR2021-00036 (July 24, 2021) (Ex. CZ).....	15
<i>Montfort-Rodriguez v. Rey-Hernandez</i> , 504 F.3d 221 (1st Cir. 2007).....	8
<i>MorphoSys AG v. Janssen Biotech, Inc.</i> , 358 F. Supp. 3d 354 (D. Del. 2019).....	16, 19
<i>Ortho-McNeil Pharm., Inc. v. Mylan Lab 'ys, Inc.</i> , 2006 WL 2865469 (D.N.J. Oct. 5, 2006), <i>aff'd</i> , 520 F.3d 1358 (Fed. Cir. 2008).....	28
<i>Pfizer Inc. v. Teva Pharms. USA, Inc.</i> , 555 F. App'x 961 (Fed. Cir. 2014).....	9
<i>PPG Indus., Inc. v. Guardian Indus. Corp.</i> , 75 F.3d 1558 (Fed. Cir. 1996).....	9
<i>Resolution Trust Corp. v. Fidelity & Deposit Co.</i> , 1998 WL 2030798 (D.N.J. Jan. 27, 1998).....	12
<i>Rosco, Inc. v. Mirror Lite Co.</i> , 304 F.3d 1373 (Fed. Cir. 2002).....	29, 30
<i>SanDisk Corp. v. Kingston Tech. Co., Inc.</i> , 863 F. Supp. 2d 815 (W.D. Wis. 2012).....	13
<i>Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.</i> , 264 F.3d 1344 (Fed. Cir. 2001).....	29, 30
<i>Soitec, S.A. v. Silicon Genesis Corp.</i> , 2002 WL 34453284 (D. Mass. Feb. 25, 2002).....	13
<i>In re Varrasso</i> , 37 F.3d 760 (1st Cir. 1994).....	8
<i>In re Wands</i> , 858 F.2d 731 (Fed. Cir. 1988).....	1, 8, 9, 16
<i>Wyeth & Cordis Corp. v. Abbott Lab 'ys</i> , 720 F.3d 1380 (Fed. Cir. 2013).....	17

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.