UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| TEVA PHARMACEUTICALS INTERNATIONAL GMBH and TEVA PHARMACEUTICALS USA, INC., | * | |
| Plaintiffs and Defendants-in-Counterclaim, | * | |
| v. | * | Civil Action No. 18-cv-12029-ADB |
| ELI LILLY AND COMPANY, | * | |
| Defendant and Plaintiff-in-Counterclaim. | * | |

**MEMORANDUM AND ORDER ON DEFENDANT'S MOTION TO TRANSFER OR STAY PENDING *INTER PARTES* REVIEW**

BURROUGHS, D.J.

In this patent infringement suit, Teva Pharmaceuticals International GmbH ("Teva GmbH") and Teva Pharmaceuticals USA, Inc. ("Teva USA" and together with Teva GmbH, "Teva") allege that Eli Lilly and Company ("Lilly") has infringed claims in nine patents owned by Teva related to a product marketed under the brand name Ajovy™, which contains the active ingredient fremanezumab and is used to treat migraines. [ECF No. 1 ("Compl.")]. Lilly has brought counterclaims against Teva, seeking declaratory judgments that its product marketed under the brand name Emgality™, which contains the active ingredient galcanezumab and is also used to treat migraines, does not infringe Teva's patents and that Teva's patents are invalid. [ECF No. 17]. Before the Court is Lilly's Motion to Transfer, or If Not Transferred, Then to Stay This Litigation Pending *Inter Partes* Review ("Motion to Transfer or Stay") [ECF No. 18]. After consideration of the parties' respective positions and taking into account the *inter partes* review ("IPR") proceedings, the Motion to Transfer or Stay is GRANTED in part and DENIED

in part. The case will not be transferred out of the District of Massachusetts, but it will be stayed pending the IPR proceedings that have been instituted.[1]

## I. BACKGROUND

### A. Factual and Procedural Background

Teva GmbH is a Swiss limited liability company with a principal place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland. [Compl. ¶ 8]. Teva USA is a Delaware corporation with a principal place of business in Pennsylvania. [Id. ¶ 9].

Lilly is an Indiana corporation with a principal place of business in Indiana. [Id. ¶ 10]. Lilly maintains a "Cambridge Innovation Center" at 450 Kendall Street, Cambridge, MA 02142, where a subset of Lilly's research and development scientists and engineers work. [Id. ¶¶ 39–43].

This action is the third in a series of cases involving Teva and Lilly's dispute over their migraine treatment drugs. See Complaint, Teva Pharms. Int'l GmbH v. Eli Lilly & Co., No. 17-cv-12087 (D. Mass. Oct. 24, 2017) ("Teva I"); Complaint, Teva Pharms. Int'l GmbH v. Eli Lilly & Co., No. 18-cv-10242 (D. Mass. Feb. 6, 2018) ("Teva II").[2]

Teva's corporate affiliate, Labrys Biologics, Inc. ("Labrys"), has conducted research on a biologic product to treat migraines with an active ingredient called fremanezumab. [Compl. ¶ 3]. Fremanezumab is a humanized monoclonal antibody that targets calcitonin gene-related peptide ("CGRP"), which is a molecule that plays a role in migraine headaches. [Id.]. Labrys' research

[1] Lilly's request to stay the action pending the decisions on whether to institute IPRs is denied as moot. See [ECF No. 19 at 26].

[2] Both of these earlier cases were dismissed for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) based on the Court's finding that there was "no controversy of sufficient immediacy and reality" at the time the complaints were filed. See Order, Teva I, No. 17-cv-12087 (D. Mass. Sept. 27, 2018), ECF No. 42 (dismissing both Teva I and Teva II).

resulted in innovations related to fremanezumab that are protected by U.S. Patents Nos. 8,586,045 ("'045 Patent"); 8,597,649 ("'649 Patent"); 9,266,951 ("'951 Patent"); 9,340,614 ("'614 Patent"); 9,346,881 ("'881 Patent"); 9,884,907 ("'907 Patent"); 9,884,908 ("'908 Patent"); 9,890,210 ("'210 Patent"); and 9,890,211 ("'211 Patent") (collectively, the "Patents-in-Suit"). [Id. ¶ 4].

The Patents-in-Suit include six patents for compositions of matter and three patents for methods of treatment. The patents for compositions of matter cover:

- "[a]n isolated human or humanized anti-CGRP antagonist antibody with a binding affinity ($K_D$) to human α-CGRP of 50 nM or less as measured by surface plasmon resonance at 37º C,"[3] [ECF No. 1-21 at 71 ('649 Patent)];
- a "human or humanized monoclonal anti-CGRP antagonist antibody that (1) binds human α-CGRP and (2) inhibits cyclic adenosine monophosphate (cAMP) activation in cells" along with the pharmaceutical composition of the same, [ECF No. 1-22 at 73 ('951 Patent)];
- a "human or humanized monoclonal anti-CGRP antagonist antibody that preferentially binds to human α-CGRP as compared to amylin" along with the pharmaceutical composition of the same, [ECF No. 1-23 at 74 ('614 Patent)];
- a "human or humanized monoclonal anti-CGRP antagonist antibody that (1) binds human α-CGRP and (2) inhibits human α-CGRP from binding to its receptor as measured by a radioligand binding assay in SK-N-MC cells," [ECF No. 1-24 at 73 ('881 Patent)];

[3] α-CGRP is one of two types of CGRP that exists in humans; the other type is β-CGRP. [ECF No. 1-21 at 21]. An anti-CGRP antagonist antibody is defined as "an antibody that is able to bind to CGRP and inhibit CGRP biological activity and/or downstream pathway(s) mediated by CGRP signaling." [ECF No. 1-20 at 27].

- a humanized monoclonal anti-CGRP antagonist antibody comprising "two human IgG heavy chains, each heavy chain comprising three complementarity determining regions (CDRs) and four framework regions, wherein portions of the two heavy chains together form an Fc region; and two light chains, each light chain comprising three CDRs and four framework regions; wherein the CDRs impart to the antibody specific binding to a CGRP consisting of amino acid residues 1 to 37 of SEQ ID NO:15 or SEQ ID NO:43,"[4] [ECF No. 1-34 at 78 ('210 Patent)]; and,
- a humanized monoclonal anti-CGRP antagonist antibody comprising "two human IgG heavy chains, each heavy chain comprising three complementarity determining regions (CDRs) and four framework regions, wherein portions of the two heavy chains together form an Fc region; and two light chains, each light chain comprising three CDRs and four framework regions; wherein the CDRs impart to the antibody specific binding to a CGRP consisting of amino acid residues 1 to 37 of SEQ ID NO:15 or SEQ ID NO:43, and wherein the antibody binds to the CGRP with a binding affinity ($K_D$) of about 10 nM or less as measured by surface plasmon resonance at 37º C, [ECF No. 1-35 at 78 ('211 Patent)].

The patents for methods of treatment include:

- a method for reducing the incidence of or treating at least one vasomotor symptom, selected from the group consisting of hot flush, a migraine with or without an aura, hemiplegic migraine, cluster headache, migrainous neuralgia, chronic headache, and tension headache, by administering a human or humanized anti-CGRP antagonist

[4] SEQ ID NO:15 refers to the amino acid sequence of human α-CGRP, and SEQ ID NO:43 refers to the amino acid sequence of human β-CGRP. [ECF No. 1-32 at 64].

antibody, [ECF No. 1-20 at 70 ('045 Patent)];

- a method for treating headache in individuals by administering an effective amount of a humanized monoclonal anti-CGRP antagonist antibody, comprised of "two human IgG heavy chains, each heavy chain comprising three complementarity determining regions (CDRs) and four framework regions, wherein portions of the two heavy chains together form an Fc region; and two light chains, each light chain comprising three CDRs and four framework regions; wherein the CDRs impart to the antibody specific binding to a CGRP consisting of amino acid residues 1 to 37 of SEQ ID NO:15 or SEQ ID NO:43," [ECF No. 1-32 at 78 ('907 Patent)]; and,
- a method for treating headache in individuals by administering an effective amount of a humanized monoclonal anti-CGRP antagonist antibody, comprised of "two human IgG heavy chains, each heavy chain comprising three complementarity determining regions (CDRs) and four framework regions, wherein portions of the two heavy chains together form an Fc region; and two light chains, each light chain comprising three CDRs and four framework regions; wherein the CDRs impart to the antibody specific binding to a CGRP consisting of amino acid residues 1 to 37 of SEQ ID NO:15 or SEQ ID NO:43, and wherein the antibody binds to the CGRP with a binding affinity ($K_D$) of about 10 nM or less as measured by surface plasmon resonance at 37º C," [ECF No. 1-33 at 76 ('908 Patent)].

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