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

STIPULATION AND [PROPOSED] ORDER
OF DISMISSAL OF CERTAIN CLAIMS AND DEFENSES

Plaintiffs Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") and Defendant Eli Lilly and Company ("Lilly"; together with Teva, "the Parties"), through their counsel, hereby stipulate and agree as follows.

WHEREAS, in its September 27, 2018 complaint in this matter, Teva asserted that Lilly's Emgality® (galcanezumab-gnlm) injection product, or uses thereof, infringes the following nine patents: U.S. Patent Nos. 8,586,045; 8,597,649; 9,266,951; 9,340,614; 9,346,881; 9,884,907; 9,884,908; 9,890,210; and 9,890,211 (collectively, "the Patents-in-Suit"). (Dkt. No. 1.)

WHEREAS, in its November 2, 2018 answer to Teva's complaint in this matter, Lilly asserted, *inter alia*, affirmative defenses that each of the Patent-in-Suit are not infringed and are invalid, as well as counterclaims seeking declaratory judgment of the same. (Dkt. No. 17.)

WHEREAS, by March 31, 2020, the United States Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") had issued final written decisions in all *Inter Partes* Review

("IPR") proceedings filed by Lilly as to certain challenged claims in each of the nine Patents-in-Suit. (*See* Dkt. No. 44.)

WHEREAS, on August 16, 2021, the U.S. Court of Appeals for the Federal Circuit issued three decisions on appeal from the PTAB's final written decisions in the nine IPR proceedings involving the Patents-in-Suit, affirming the PTAB's findings that (1) the challenged claims of six[1] of the Patents-in-Suit are unpatentable as obvious and (2) the challenged claims of the remaining three[2] Patents-in-Suit are not unpatentable as obvious on the single obviousness ground considered. (*See* Dkt. Nos. 140, 141.)

WHEREAS the parties have met and conferred and have reached an agreement to narrow the issues pending in this matter in view of the recent Federal Circuit decisions.

WHEREAS Teva has agreed to withdraw its infringement allegations against Lilly based on the six Patents-in-Suit that contain claims that were affirmed as unpatentable as obvious by the Federal Circuit;

WHEREAS the infringement allegations Teva brought against Lilly based on the three Patents-in-Suit with claims that were affirmed by the Federal Circuit as not unpatentable remain before this Court;

WHEREAS Lilly has agreed to withdraw its allegations, set forth in its preliminary patent-related disclosures pursuant to Local Rule 16.6(d), that the asserted claims in the remaining three Patents-in-Suit are invalid as anticipated under 35 U.S.C. § 102 by Tan, Application of Monoclonal Antibodies to the Investigation of the Role of Calcitonin Gene-Related Peptide as a Vasodilatory Neurotransmitter, Dissertation Submitted to the University of Cambridge (1994) ("the Tan Thesis")

[1] The challenged claims are: claims 1-7 and 15-20 of U.S. Patent No. 9,340,614; claims 1-6 and 14-19 of U.S. Patent No. 9,266,951; claims 1-15 of U.S. Patent No. 9,890,210; claims 1-6 and 14-19 of U.S. Patent No. 9,346,881; claims 1-15 of U.S. Patent No. 9,890,211; and claims 1-9 of U.S. Patent No. 8,597,649.
[2] The challenged claims are: claims 1, 3, 4, 8-17, 19, 20, and 24-31 of U.S. Patent Nos. 8,586,045; claims 1-18 of U.S. Patent No. 9,884,907; and claims 1-18 of U.S. Patent No. 9,884,908.

and/or rendered obvious under 35 U.S.C. § 103 by the Tan Thesis alone or in combination with one or more of the following references:

- Lassen et al., CGRP May Play a Causative Role in Migraine, Cephalalgia (2002) 22: 54-61 ("Lassen");
- Doods et al., Pharmacological Profile of BIBN4096BS, the First Selective Small Molecule CGRP Antagonist, Br. J. Pharmacol. (2000) 129: 420-423 ("Doods");
- Olesen et al., Calcitonin Gene-Related Peptide Receptor Antagonist BIBN 4096 BS for the Acute Treatment of Migraine, N. Engl. J. Med. (2004) 350: 1104-1110 ("Olesen");
- Petersen et al., BIBN4096BS Antagonizes Human α-Calcitonin Gene Related Peptide-Induced Headache and Extracerebral Artery Dilation, Clinical Pharmacology & Therapeutics: (2005) 77(3): 202-213 ("Petersen 2005");
- Messlinger et al., Inhibition of Neurogenic Blood Flow Increases in the Rat Cranial Dura Mater by a CGRP-Binding Spiegelmer, Cephalalgia (2005) 25: 923 (F022) ("Messlinger");
- Covell et al., Pharmacokinetics of Monoclonal Immunoglobulin G1, F(ab')2, and Fab' in Mice, Cancer Res. (1986) 46: 3969-3978 ("Covell");
- Wimalawansa, Calcitonin Gene-Related Peptide and its Receptors: Molecular Genetics, Physiology, Pathophysiology, and Therapeutic Potentials, 17 Endocrine Reviews 5, 533–85 (1996) ("Wimalawansa"); and
- Queen et al., U.S. Patent No. 6,180,370 B1, issued Jan. 30, 2001 ("Queen");

WHEREAS the Parties' aforementioned agreement renders moot any potential motion for summary judgment, by Teva, that Lilly is "statutorily estopped from asserting prior art based invalidity defenses" as to the asserted claims of the three Patents-in-Suit upheld by the Federal Circuit. (Dkt. No. 141.)

NOW, THEREFORE, IN RECOGNITION OF THE FEDERAL CIRCUIT'S DECISIONS ON APPEAL FROM THE IPR PROCEEDINGS, IT IS HEREBY STIPULATED AND AGREED, by and between the Parties hereto, and subject to the approval of the Court, as follows:

A. All claims, counterclaims, and defenses relating to U.S. Patent Nos. 8,597,649; 9,266,951; 9,340,614; 9,346,881; 9,890,210; or 9,890,211 in Teva's Complaint (Dkt. No. 1), Lilly's

Answer to Teva's Complaint (Dkt No. 17), and Teva's Answer to Counterclaims (Dkt. No. 25) are hereby dismissed with prejudice.[3]

B. Lilly will not assert that U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908 are invalid as anticipated under 35 U.S.C. § 102 by the Tan Thesis or rendered obvious under 35 U.S.C. § 103 by the Tan Thesis alone or in combination with one or more of Lassen, Doods, Olesen, Petersen 2005, Messlinger, Covell, Wimalawansa, and Queen, and hereby withdraws the corresponding portions of its preliminary patent-related disclosures pursuant to Local Rule 16.6(d).[4]

C. The Parties shall bear their own costs and attorney fees in connection with the claims and defenses dismissed or withdrawn by this Stipulation and Order.

IT IS SO STIPULATED:

Dated: September 15, 2021

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[3] For the avoidance of doubt, these claims, counterclaims, and defenses include Counts II-V, VIII-IX, XI-XIV, and XVII-XVIII in Teva's Complaint (Dkt. No. 1), Counts III-X and XV-XVIII of Lilly's Counterclaims as well as Lilly's Third-Tenth and Fifteenth-Eighteenth Affirmative Defenses in Lilly's Answer to Teva's Complaint (Dkt No. 17). Further, Counts XIX and XX of Lilly's Counterclaims as well as Lilly's Twenty-Second, Twenty-Third, and Twenty-Fourth Affirmative Defenses in Lilly's Answer to Teva's Complaint (Dkt No. 17) are hereby dismissed with prejudice, in part, to the extent they relate to U.S. Patent Nos. 8,597,649; 9,266,951; 9,340,614; 9,346,881; 9,890,210; or 9,890,211.

[4] For the avoidance of doubt, Lilly maintains its assertions, set forth in its preliminary patent-related disclosures pursuant to Local Rule 16.6(d), that U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908 are invalid for, *inter alia*, improper inventorship and derivation under 35 U.S.C. § 102(f) as well as for statutory and obviousness-type double patenting. For the further avoidance of doubt, nothing in this Stipulation and Order precludes the parties from referencing the claims, counterclaims and defenses dismissed hereby with prejudice, or the content of the Federal Circuit decisions pertaining to the patents and assertions covered by those claims, counterclaims, and defenses.

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