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 **ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF DEFENDANT ELI LILLY AND COMPANY**

LILLY'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT

Defendant Eli Lilly and Company ("Lilly") respectfully submits this answer, affirmative defenses, and counterclaims to the Complaint filed by Plaintiffs Teva Pharmaceuticals International GmbH ("Teva GmbH") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Plaintiffs" or "Teva"), and states as follows:

NATURE OF THE ACTION

1. Teva brings this action to protect its intellectual property rights covering breakthrough treatments for migraine headaches. Teva has invested heavily in this innovative technology, and the potential benefit to the public is enormous. Over 1 billion people suffer from migraine headaches worldwide. More than 38 million people experience migraine headaches in the United States alone.

ANSWER: Lilly admits, on information and belief, that over 1 billion people suffer from migraine headaches worldwide, and more than 38 million people experience migraine headaches in the United States alone. Lilly admits that Teva filed a Complaint for Patent Infringement against Lilly on September 27, 2018. Lilly is otherwise without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 1 of

the Complaint, and therefore denies the same.

2. Migraine is a complex, common neurological condition that is characterized by severe, episodic attacks of headache. Migraine can also cause nausea, vomiting, and sensitivity to light, sound, or movement. In the United States and Western Europe, over 10% of the general population suffers from migraine.

ANSWER: Lilly admits the allegations of Paragraph 2 of the Complaint on information and belief.

3. Teva's corporate affiliate, Labrys Biologics, Inc. ("Labrys"), made a major breakthrough in research for migraine treatment. Through years of painstaking study, Labrys made important discoveries concerning the role that calcitonin gene-related peptide ("CGRP") plays in migraine headaches. Armed with that knowledge, Labrys developed a biologic product with an active ingredient, fremanezumab—a humanized monoclonal antibody that targets CGRP. This new product has been shown to prevent and/or reduce the incidence of migraines. Fremanezumab has the potential to help tens of millions of migraine sufferers in the United States.

ANSWER: Lilly admits that the FDA has approved Ajovy™ (fremanezumab-vfrm) injection for the preventive treatment of migraine in adults, and the Patient Information for Ajovy™ states that the active ingredient in Ajovy is fremanezumab-vfrm. Lilly further admits that the Full Prescribing Information for Ajovy™ states that "[f]remanezumab-vfrm is a humanized monoclonal antibody that binds to calcitonin gene-related peptide (CGRP) ligand and blocks its binding to the receptor." Lilly is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of the Complaint, and therefore denies the same.

4. Labrys' innovations are protected by at least 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 ("the Patents-in-Suit"). Labrys assigned the Patents-in-Suit to Teva on September 19, 2016. Teva, in turn, has continued to invest in fremanezumab to bring the product to market. On October 16, 2017, Teva Branded Pharmaceutical Products R&D, Inc. submitted a Biologics License Application ("BLA") to the Food and Drug Administration ("FDA") seeking approval to market fremanezumab for the treatment of episodic and chronic migraine. On or about March 22, 2018, Teva Branded Pharmaceuticals Products R&D, Inc. transferred the BLA seeking approval to market fremanezumab for the treatment of episodic and chronic migraine to Teva Pharmaceuticals USA, Inc. On September 19, 2018, Teva received FDA approval to market

fremanezumab in the United States under the brand name Ajovy™. *See* Ex. 28. Teva Pharmaceuticals USA, Inc. is the exclusive distributor of Ajovy™ within the United States.

ANSWER: On October 17, 2017, Teva Pharmaceutical Industries Ltd., announced that a BLA for fremanezumab for the preventative treatment of migraine had been submitted to FDA. On September 14, 2018, Teva Pharmaceutical Industries Ltd., announced that the FDA approved Ajovy™ (fremanezumab-vfrm) injection for the preventive treatment of migraine in adults. Lilly is otherwise without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 4 of the Complaint, and therefore denies the same.

5. Eli Lilly is aware of the Patents-in-Suit, but nonetheless is, upon information and belief, in the process of launching its own competing biologic product with the active ingredient galcanezumab, which will undermine the value of Teva's substantial investment in the Patents-in-Suit. This product is also known as LY2951742 (the "Galcanezumab Product"). Like Teva's patented fremanezumab product, Eli Lilly's infringing Galcanezumab Product is an antibody that targets CGRP. On October 24, 2017, Eli Lilly publicly stated that it had submitted its own BLA for the Galcanezumab Product. Ex. 1 at 3. Through its public statements and commercial activity, Eli Lilly made clear that it intended to enter the market with its Galcanezumab Product as soon as it received FDA approval.

ANSWER: Lilly admits that it is aware of 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 ("the Patents-in-Suit"), but denies that the marketing of a biologic product with the active ingredient galcanezumab would infringe any valid and enforceable claim of the Patents-in-Suit. Lilly admits that on October 24, 2017, on its third-quarter earnings call, Lilly stated that "[w]e submitted the BLA for galcanezumab for migraine prevention" and that it was a "U.S. submission." Lilly denies that Lilly's biologic product with the active ingredient galcanezumab is also known as LY2951742 (defined by Teva herein as the "Galcanezumab Product"). Except as expressly admitted, Lilly denies the remaining allegations of Paragraph 5 of the Complaint.

6. On September 27, 2018, Eli Lilly obtained FDA approval to market its Galcanezumab Product in the United States under the brand name Emgality™. *See* Ex. 29. The Eli Lilly press release describing the approval states that "Emgality will be available to patients shortly after

approval." *Id.* This demonstrates that the commercial launch of Emgality™ is imminent, and upon information and belief, Lilly is offering for sale, selling, manufacturing and/or importing, Emgality™ into the United States.

ANSWER: Lilly admits that on September 27, 2018, the FDA approved Emgality™ (galcanezumab-gnlm) 120 mg injection for the preventive treatment of migraine in adults, and Lilly subsequently launched Emgality™ (galcanezumab-gnlm) in the United States. Lilly further admits that the press release attached to the Complaint as Exhibit 29 states "Emgality will be available to patients shortly after approval." Lilly denies that Lilly's biologic product with the active ingredient galcanezumab is also known as LY2951742 (defined by Teva herein as the "Galcanezumab Product"). Except as expressly admitted, Lilly denies the remaining allegations of Paragraph 6 of the Complaint.

7. Eli Lilly's commercial manufacture, importation, offers to sell, and sales of its Galcanezumab Product will directly infringe, and/or will actively induce and/or contribute to infringement of, claims of each of the Patents-in-Suit. Teva files this action to recover damages suffered as result of Lilly's infringing conduct, to secure a judicial declaration that Eli Lilly has infringed the Patents-in-Suit, and to prevent Eli Lilly from any future infringement.

ANSWER: Lilly admits that Teva filed this infringement action and this declaratory judgment action for patent infringement of the Patents-in-Suit alleging that Lilly has or will directly infringe, or induce and/or contribute to infringement of the Patents-in-Suit. Paragraph 7 of the Complaint contains legal conclusions to which no response is required. To the extent any response is required, Lilly denies those allegations. Lilly denies that Lilly has or will directly infringe, or induce and/or contribute to infringement of, any valid and enforceable claim of the Patents-in-Suit. Lilly denies that Lilly's biologic product with the active ingredient galcanezumab is also known as LY2951742 (defined by Teva herein as the "Galcanezumab Product"). Except as expressly admitted, Lilly denies the remaining allegations of Paragraph 7 of the Complaint.

THE PARTIES

8. Teva GmbH is a limited liability company organized and existing under the laws of Switzerland, having its corporate offices and principal place of business at Schlüsselstrasse 12, Jona (SG) 8645, Switzerland. Teva GmbH owns the Patents-in-Suit.

ANSWER: Lilly admits, on information and belief, that Teva GmbH is a limited liability company existing under the laws of Switzerland. As to the remaining allegations contained in Paragraph 8 of the Complaint, Lilly is without knowledge or information sufficient to form a belief as to their truth, and therefore denies the same.

9. Teva USA is a Delaware corporation organized and existing under the laws of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA holds an exclusive license to the Patents-in-Suit.

ANSWER: Lilly admits, on information and belief, that Teva USA is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. As to the remaining allegations contained in Paragraph 9 of the Complaint, Lilly is without knowledge or information sufficient to form a belief as to their truth, and therefore denies the same.

10. Upon information and belief, Eli Lilly is a corporation organized and existing under the laws of the State of Indiana. Eli Lilly has corporate offices at Corporate Center, Indianapolis, Indiana 46285. Eli Lilly also has regular and established places of business in other jurisdictions, including in the Commonwealth of Massachusetts.

ANSWER: Lilly admits that it is a corporation organized and existing under the laws of the State of Indiana. Paragraph 10 of the Complaint contains legal conclusions to which no response is required. To the extent any response is required, Lilly admits that it has U.S. locations in other jurisdictions, including at 450 Kendall Street, Cambridge, Massachusetts, 02142, but denies the remaining allegations of Paragraph 10 of the Complaint.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C.

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