UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS INTERNATIONAL GMBH, and TEVA PHARMACEUTICALS USA, INC., Plaintiffs/Counterclaim Defendants v. ELI LILLY AND COMPANY, Defendant/Counterclaim Plaintiff	Civil Action No. 1:18-CV-12029-ADB

PLAINTIFFS' ANSWER TO DEFENDANT'S COUNTERCLAIMS

Plaintiffs Teva Pharmaceuticals International GmbH ("Teva GmbH") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Counterclaim-Defendants" or "Teva") by and through the undersigned attorneys, answers the Counterclaims of Defendant Eli Lilly and Company ("Lilly" or "Counterclaim-Plaintiff") in Lilly's Answer and Affirmative Defenses to Plaintiffs' Complaint (D.I. 17), as follows:

THE PARTIES[1]

1. Counterclaim-Plaintiff Eli Lilly and Company is an Indiana Corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

ANSWER:

Upon information and belief, Teva admits that Counterclaim-Plaintiff Eli Lilly and

[1] For ease of reference, Teva includes the headings contained in Lilly's Answer and Affirmative Defenses to Plaintiffs' Complaint. Although Teva believes that no response is necessary for each of those headings, to the extent a response is required and that the headings could be construed to contain factual allegations, Teva denies the allegations.

Company is an Indiana Corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

2. Upon information and belief, Counterclaim-Defendant 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.

ANSWER:

Admitted.

3. Upon information and belief, Counterclaim Defendant 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.

ANSWER:

Admitted.

JURISDICTION AND VENUE

4. These counterclaims arise under the Patent Laws of the United States and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Paragraph 4 states legal conclusions to which no response is required. To the extent that a response is required, Teva admits that Lilly's counterclaims purport to bring an action under the Patent Laws of the of the United States and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Paragraph 5 states legal conclusions to which no response is required. To the extent that a response is required and for the purposes of this action only, Teva does not contest that this Court has jurisdiction over the subject matter of this action.

6. This Court has personal jurisdiction over Counterclaim-Defendants because

Counterclaim-Defendants have availed themselves of the rights and privileges of this forum by bringing this civil action in this judicial district.

ANSWER:

Paragraph 6 states legal conclusions to which no response is required. To the extent that a response is required, Teva does not contest this Court's personal jurisdiction in this judicial district for the limited purpose of this action only. Teva admits that it brought this civil action in this judicial district.

7. To the extent that venue is appropriate for Counterclaim-Defendants' claims against Lilly, venue is also appropriate in this Court for Lilly's counterclaims. Venue is also proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b) and 1391(c).

ANSWER:

Paragraph 7 states legal conclusions to which no response is required. To the extent that a response is required and for the purposes of this action only, Teva does not contest that venue in this judicial district is proper for Lilly's counterclaims.

FACTUAL BACKGROUND

A. Lilly' Migraine Treatment: Emgality (galcanezumab-gnlm)

8. Migraine is a debilitating neurologic disorder that affects roughly one in seven Americans annually. It imposes a profound socioeconomic burden on society through healthcare costs and loss of productivity. For individual sufferers, migraine significantly impairs quality of life and ability to function, often resulting in disability.

ANSWER:

Upon information and belief, Teva admits the allegations in Paragraph 8 of the Counterclaim.

9. Lilly is a global healthcare leader that has been committed to the discovery and development of life-changing medicines for more than 140 years. Lilly's research has both accelerated the understanding of migraine and advanced development of therapeutic agents to treat migraine. Lilly has investigated more than a dozen different compounds for the treatment of migraine and disabling headache disorders. Two of those compounds, lasmiditan and galcanezumab, are currently in clinical trials.

ANSWER:

Teva admits that Lilly has conducted clinical trials for its application for FDA approval to market a product with the active ingredient galcanezumab ("Galcanezumab Product") in the United States. Teva lacks sufficient information to admit or deny the remaining allegations of this paragraph and therefore, denies them.

10. Lilly's original research on galcanezumab dates back at least a dozen years. After conducting extensive preclinical screening and safety testing, Lilly designed and conducted multiple large-scale clinical trials to evaluate the safety and efficacy of galcanezumab to prevent and treat migraine. These trials have demonstrated therapeutic potential.

ANSWER:

Teva admits that Lilly has conducted clinical trials for its application for FDA approval to market the Galcanezumab Product in the United States. Teva lacks sufficient information to admit or deny the remaining allegations of this paragraph and therefore, denies them.

11. On October 24, 2017, Lilly announced that it had submitted a Biologics License Application ("BLA") to the FDA to market Emgality™ (galcanezumab-gnlm) for the prevention of migraine. On September 27, 2018, the FDA approved Emgality™ (galcanezumab-gnlm) 120 mg injection for the preventive treatment of migraine in adults.

ANSWER:

Teva admits that on October 24, 2017, Lilly publicly stated that it had submitted a BLA to the FDA to market the Galcanezumab Product. Teva admits that on September 27, 2018 Lilly obtained FDA approval to market its Galcanezumab Product in the United States under the brand name Emgality™ 120 mg for the preventive treatment of migraine in adults. Teva lacks sufficient information to admit or deny the remaining allegations of this paragraph and therefore, denies them.

B. Teva's Migraine Treatment: Ajovy™ (fremanezumab)

12. On information and belief, fremanezumab was originally discovered and developed at Rinat Neuroscience. On information and belief, Pfizer acquired Rinat in 2006, continued research and development of fremanezumab, including conducting a Phase I clinical trial of fremanezumab.

ANSWER:

Upon information and belief, Teva admits fremanezumab was originally discovered at Rinat Neuroscience, that Pfizer acquired Rinat in 2006, and that Pfizer began clinical development of fremanezumab. Teva lacks sufficient information to admit or deny the remaining allegations of this paragraph and therefore, denies them.

13. On information and belief, in 2013 Labrys Biologics, Inc. ("Labrys") acquired the rights to fremanezumab from Pfizer. On information and belief, Labrys continued to develop fremanezumab, including conducting additional clinical trials in humans.

ANSWER:

Upon information and belief, Teva admits that in 2012 Pfizer assigned rights to fremanezumab to Labrys. Teva admits that Labrys continued development of fremanezumab including conducting clinical trials in humans. Teva denies any remaining allegations in

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