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. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Teva Pharmaceuticals International GmbH ("Teva GmbH") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Plaintiffs" or "Teva") bring this action for patent infringement and declaratory judgment against Defendant Eli Lilly and Company ("Eli Lilly").

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.

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.

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.

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.

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.

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.

7. Eli Lilly's commercial manufacture, importation, offers to sell, and sales of its Galcanezumab Product will directly infringe, and/or 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.

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.

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

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.

JURISDICTION AND VENUE

11. 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.

12. This Court has personal jurisdiction over Eli Lilly because Eli Lilly has extensive contacts with the Commonwealth of Massachusetts that directly relate to this suit.

13. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) because Eli Lilly resides in this District. *See* 28 U.S.C. § 1391(c)(2). Venue is also proper in this Judicial District pursuant to 28 U.S.C. § 1400(b) because Eli Lilly has a regular and established place of business in Massachusetts and is committing (or will imminently commit) acts of infringement in the Commonwealth based on the FDA approval and commercial launch of its Galcanezumab Product.

A. Eli Lilly Has Received FDA Approval, Allowing the Immediate Commercial Launch of its Galcanezumab Product.

14. There is an actual controversy regarding Eli Lilly's infringement of the Patents-in-Suit by commercially manufacturing, offering to sell, and selling the Galcanezumab Product. Eli Lilly engaged in extensive preparations to bring its Galcanezumab Product to market in the immediate future, including submitting a BLA to the FDA for approval to market and sell the Galcanezumab Product for the prevention of both episodic and chronic migraine.

15. Over the course of the past year, Eli Lilly made many public statements representing that it expected to receive FDA approval of its Galcanezumab Product and indicating that it planned to commercially launch the Galcanezumab Product as soon as the

FDA approved its BLA.

16. Eli Lilly has completed all of the Phase III clinical trials it believes are necessary to support its application for FDA approval to market the Galcanezumab Product in the United States. On October 24, 2017, Eli Lilly confirmed that it submitted a BLA with the FDA to market and sell the Galcanezumab Product for the prevention of both episodic and chronic migraine. This filing signaled a serious commitment by Eli Lilly to imminently launch the Galcanezumab Product, because filing a BLA represents a substantial undertaking and investment.

17. Eli Lilly publicly expressed confidence that the FDA would approve its BLA in 2018. Eli Lilly made these statements in a special call with investors and at the Annual J.P. Morgan Healthcare Conference. *See* Ex. 2 at 19-20; Ex. 3 at 19. Several of these statements were made by C-level executives at Eli Lilly. In its June 28, 2017 Form 10-Q submitted to the U.S. Securities and Exchange Commission, Eli Lilly identified the Galcanezumab Product as being in Eli Lilly's "late-stage pipeline." Ex. 4 at 38.

18. Eli Lilly publicly confirmed that it had incorporated the expected launch of its Galcanezumab Product into its long-term revenue growth guidance for investors. For example, during the question and answer portion of a July 25, 2017 Eli Lilly earnings call, Eli Lilly CFO and Executive VP of Global Services, Derica Rice, responded to the question "[o]n galcanezumab . . . is the launch reflected in your long-term revenue growth guidance?" by saying "[y]es, the simple answer is yes." Ex. 5 at 20, 21.

19. Eli Lilly's expectation that it would receive FDA approval to market the Galcanezumab Product in the very near future was consistent with the FDA's practice for reviewing and approving BLAs. In 2016, the median total approval time for BLAs from the date of filing was just 10.1 months. *See* Ex. 6 at 1. In fact, the FDA has established a goal of

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