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

acting on 90% of BLAs within 10 months of the 60-day filing date (the 60-day filing date is the window of time in which the FDA decides whether to accept an application for substantive review). *See* Ex. 7 at 4.

20. On September 21, 2018, Eli Lilly issued a press release announcing that "the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for Emgality™ (galcanezumab) for the prophylaxis of migraine in adults who have at least four migraine days per month." Ex. 36 at 1. Eli Lilly characterized this result as "the first regulatory step toward approval for Emgality in Europe." *Id.* This press release also addressed the FDA approval process for Emgality™ in the United States and stated that "a decision regarding approval is expected by the end of September 2018." *Id.*

21. Eli Lilly's efforts culminated in the announcement on September 27, 2018 that FDA had approved Eli Lilly's BLA, clearing the way for the commercial launch of the Galcanezumab Product in the United States. *See* Ex. 29.

B. Commercial Sales of The Galcanezumab Product Are Imminent.

22. Even before receiving FDA approval, Eli Lilly engaged in extensive preparations to allow for an immediate commercial launch of its Galcanezumab Product following FDA approval. For example, Eli Lilly instituted substantial marketing efforts directed at healthcare providers to raise awareness of migraine treatment, developed education materials about migraine, and built a sales force to launch the Galcanezumab Product. These activities are generally undertaken by a pharmaceutical company when a product's launch is imminent. Eli Lilly engaged in these efforts in the United States generally and in Massachusetts specifically.

23. Eli Lilly invested heavily in developing an online presence directed to healthcare

providers, in the United States and Massachusetts, to promote migraine treatments and CGRP's role in migraine. For example, Eli Lilly established a Twitter account named @LillyMigraine in June 2017. *See* Ex. 8 at 1 ("Lilly Migraine U.S. @LillyMigraine," TWITTER, https://twitter.com/lillymigraine (last visited Oct. 24, 2017)).

24. As early as October 2017, Eli Lilly was building a sales force to support the launch of its Galcanezumab Product, including in Massachusetts specifically. Eli Lilly's job board listed open positions for twenty-five sales representative positions who would be assigned to market the Galcanezumab Product once it is approved by the FDA. At least one of those positions was in Massachusetts. For example, Eli Lilly advertised a "Sales Representative—Neuroscience" position for "Boston, Massachusetts." Eli Lilly's job board stated that "[u]pon the anticipated approval of Galca [*i.e.*, the Galcanezumab Product], this position will primarily focus on the successful launch of Galca." *See* Ex. 10 at 2.

25. On June 27, 2018, Eli Lilly announced that the FDA conditionally accepted a brand name for its Galcanezumab Product—Emgality™. Ex. 30 at 1. Eli Lilly has filed trademark applications with the U.S. Patent and Trademark Office to protect the Emgality™ name and logo, and received Notices of Allowance for these marks on June 6, 2017, and October 17, 2017, respectively. Ex. 31.

C. Eli Lilly Knows Its Galcanezumab Product Infringes The Patents-in-Suit.

26. Eli Lilly tracks and follows Teva's patents related to the treatment of migraine as it relates to CGRP. For that reason, Teva is informed and believes that Eli Lilly knows about the Patents-in-Suit and the barrier that they pose to commercially launching the Galcanezumab Product in the United States.

27. On July 16, 2014, Eli Lilly initiated an opposition to European Patent No. 1957106 B1, titled "Antagonist antibodies directed against calcitonin gene-related peptide and

methods using the same" ("EP 1957106"). Ex. 11. Eli Lilly knows that EP 1957106 has important implications for its Galcanezumab Product. The background section of Eli Lilly's opposition filing describes the role of CGRP in migraine and the history and shortcomings of small molecule (i.e., non-biologic) treatments for migraine. *Id*. at 4-5. The opposition also notes Eli Lilly's belief that EP 1957106 "provide[s] a very broad scope of protection" that "encompasses almost all anti-CGRP antagonist antibodies that may have therapeutic utility." *Id*. at 9.

28. Eli Lilly also knows that there are United States patents in the same family as EP 1957106, including the Patents-in-Suit. EP 1957106 claims a related invention to the Patents-in-Suit, and Eli Lilly noted in its opposition papers that EP 1957106 claims priority to provisional U.S. Application No. 60/736,623 ("the '623 application"). Ex. 11 at 2. All of the Patents-in-Suit also claim priority to the '623 application, and several of the applications that issued as the Patents-in-Suit had already been published by the United States Patent Office before Eli Lilly submitted its opposition to EP 1957106. All of the applications that issued as the Patents-in-Suit were published by the end of 2015, before Eli Lilly submitted additional opposition papers throughout 2016 that continued to reference the '623 application. Ex. 12 at 9- 10; Ex. 11 at 11. In February 2017, the European Patent Office found that EP 1957106 is entitled to the priority date of the '623 application. Ex. 13 at Sheet 9-11.

29. Upon information and belief, Eli Lilly pressed ahead with its BLA filing even though it knows that its Galcanezumab Product infringes the Patents-in-Suit. During a June 19, 2017, "special call" with investors, Eli Lilly Global Brand Development Leader for Migraine, Robert Conley, responded to a question asking whether Eli Lilly "intend[s] to file" for approval of its Galcanezumab Product "in Europe given the patent issues" and whether he thought "those patent issues are relevant in the U.S." by stating that, considering "the specifics of this case,"

Eli Lilly "certainly [is] planning . . . on FDA submission." *See* Ex. 14 at 10-11.

30. Eli Lilly also continued to pursue approval of its BLA even after Teva filed actions seeking declaratory relief that Eli Lilly's planned commercial launch of the Galcanezumab Product would infringe the Patents-in-Suit.

31. Eli Lilly has already created a case and controversy regarding the validity of six of the nine patents-in-suit by initiating *Inter Partes* Review ("IPR") proceedings against these patents before the Patent Trial and Appeal Board ("PTAB"). Because, as described above, Eli Lilly knows its Galcanezumab Product will infringe these patents, these IPR filings demonstrate that commercial launch of the Galcanezumab Product is imminent.

32. On August 8, 2018, Eli Lilly filed six individual IPR petitions alleging that U.S. Patent Nos. 8,597,649, 9,266,951, 9,340,614, 9,266,951, 9,346,881, 9,890,210, 9,890,211, are each invalid as obvious. The IPR docket numbers corresponding to Eli Lilly's filings against each of these Patents-in-Suit are, respectively, IPR2018-01427, IPR2018-01423, IPR2018-01422, IPR2018-01424, IPR2018-01425, and IPR2018-01426. As described in detail below, Teva asserts that Eli Lilly's Galcanezumab Product infringes each of these six Patents-in-Suit.

D. Eli Lilly Has A Substantial And Continuous Presence In This Judicial District And Intends To Commit Acts Of Infringement In Massachusetts.

33. Eli Lilly has extensive contacts with the Commonwealth of Massachusetts and is actively engaged in the business of marketing and selling pharmaceutical products in Massachusetts. Moreover, this suit is directly related to Eli Lilly's contacts with Massachusetts.

1. Eli Lilly Has A Long History Connecting Its Business To Massachusetts.

34. Eli Lilly is registered to do business in the Commonwealth of Massachusetts

and has designated National Registered Agents, Inc., 155 Federal Street, Suite 700, Boston, MA 02110 as its registered agent for service of process in Massachusetts. *See* Ex. 15 at 1.

35. Eli Lilly filed a Foreign Corporation Certificate of Registration in the Commonwealth of Massachusetts. As a registered Foreign Corporation, Eli Lilly is required to file Annual Reports with the Commonwealth.

36. In its January 24, 2017 Annual Report filed with Massachusetts, Eli Lilly described its business in the Commonwealth as "pharmaceutical manufacturing and sales." *See* Ex. 15 at 2.

37. Eli Lilly has dozens of pharmaceutical drug products that it currently markets, sells, and distributes in Massachusetts. *See* Ex. 16 ("Products," ELI LILLY AND COMPANY, https://www.lilly.com/products (last visited September 27, 2018)).

38. Eli Lilly also employs consultants and sales people in Massachusetts to work with Massachusetts healthcare providers.

2. Eli Lilly Has A Regular And Established Place Of Business In Massachusetts.

39. As of October 24, 2017, Eli Lilly's public website lists the following address as one of its "U.S. Locations:"

> Cambridge, MA
> Eli Lilly and Company 450 Kendall Street
> Cambridge, MA 02142
> +1-617-225-3226

See Ex. 17 at 1.

40. The Cambridge, Massachusetts address is home to Eli Lilly's "Cambridge Innovation Center" ("Innovation Center"). The Innovation Center serves as a location for the company's research and development efforts with respect to drug delivery and device innovation. This Innovation Center includes research into treatments for pain and biologics

that require injections.

41. In a May 6, 2015 video discussing the Innovation Center, Eli Lilly Vice President of Delivery and Device Research, Divakar Rmakrishnan, explained that the Innovation Center was created to employ "a subset of [Eli Lilly's] R&D Group." *See* Ex. 18 (Introducing Lilly's Cambridge Innovation Center Video, at 0:00 to 0:18, ELI LILLY AND COMPANY, May 6, 2015, *available at* https://careers.lilly.com/Cambridge-Innovation-Center).

42. On May 6, 2015, Eli Lilly issued a press release concerning the Innovation Center. Eli Lilly's then Chairman, President, and CEO John Lechleiter made numerous public statements about the Innovation Center. Ex. 19.

43. Mr. Lechleiter stated that Eli Lilly planned to employ "about 30 scientists and engineers" at the Innovation Center, which would increase Eli Lilly's "delivery and device research and development space by nearly 50 percent, while increasing its staff by 25 percent." *See id.* at 1.

44. Mr. Lechleiter announced in that press conference that "[n]ew drug delivery and device innovation is critically important to Lilly's growing portfolio of potential medicines, particularly in our focus areas," which includes treatments for "pain." *Id.* The press release added that "[m]ore than half of the company's pipeline now comprises biologics that require some type of injection" and that "[t]he company expects its revenues from device-enabled products to double by 2020." *Id.*

45. The Galcanezumab Product is a biologic product that is administered by injection and, upon information and belief, is part of the Innovation Center's mandate.

THE PATENTS-IN-SUIT

A. U.S. Patent No. 8,586,045

46. On November 19, 2013, United States Patent No. 8,586,045 ("the '045 patent"),

titled "Methods of Using Anti-CGRP Antagonist Antibodies," issued to Labrys Biologics, Inc. as assignee of the named inventors Joerg Zeller, Kristian T. Poulsen, Yasmina N. Abdiche, Jaume Pons, Sierra Leigh Jones Collier, and Arnon Rosenthal. A copy of the '045 patent is attached as Exhibit 20.

47. On July 21, 2014, Labrys Biologics, Inc. was acquired by Teva Pharmaceuticals USA, Inc. A confirmatory assignment of the '045 patent from Labrys to Teva Pharmaceuticals International GmbH was executed on September 19, 2016. The '045 patent is valid and enforceable.

48. The claims of the '045 patent are directed to methods for reducing incidence of or treating at least one vasomotor symptom including, for example, headache in an individual. These methods comprise administering to the individual an effective amount of a human or humanized anti-CGRP antagonist antibody.

49. An anti-CGRP antagonist antibody is able to bind to CGRP and inhibit CGRP biological activity and/or downstream pathway(s) mediated by CGRP signaling.

50. The '045 patent states that vasomotor symptoms include migraine.

B. U.S. Patent No. 8,597,649

51. On December 3, 2013, United States Patent No. 8,597,649 ("the '649 patent"), titled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide and Methods Using Same," issued to Labrys Biologics, Inc. as assignee of the named inventors Joerg Zeller, Kristian T. Poulsen, Yasmina N. Abdiche, Jaume Pons, Sierra Leigh Jones Collier, and Arnon Rosenthal. A copy of the '649 patent is attached as Exhibit 21.

52. A confirmatory assignment of the '649 patent from Labrys to Teva was executed on September 19, 2016. The '649 patent is valid and enforceable.

53. The claims of the '649 patent are directed to an 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.

C. U.S. Patent No. 9,266,951

54. On February 23, 2016, United States Patent No. 9,266,951 ("the '951 patent"), titled "Antagonist antibodies directed against calcitonin gene-related peptide and methods using same," issued to Labrys Biologics, Inc. as assignee of the named inventors Joerg Zeller, Kristian T. Poulsen, Yasmina N. Abdiche, Jaume Pons, Sierra Leigh Jones Collier, and Arnon Rosenthal. A copy of the '951 patent is attached as Exhibit 22.

55. A confirmatory assignment of the '951 patent from Labrys to Teva was executed on September 19, 2016. The '951 patent is valid and enforceable.

56. The claims of the '951 patent are directed to a human or humanized monoclonal anti-CGRP antagonist antibody that binds human α-CGRP and inhibits cyclic adenosine monophosphate (cAMP) activation in cells.

D. U.S Patent No. 9,340,614

57. On May 17, 2016, United States Patent No. 9,340,614 ("the '614 patent"), titled "Antagonist antibodies directed against calcitonin gene-related peptide and methods using same," issued to Labrys Biologics, Inc. as assignee of the named inventors Joerg Zeller, Kristian T. Poulsen, Yasmina N. Abdiche, Jaume Pons, Sierra Leigh Jones Collier, and Arnon Rosenthal. A copy of the '614 patent is attached as Exhibit 23.

58. A confirmatory assignment of the '614 patent from Labrys to Teva was executed on September 19, 2016. The '614 patent is valid and enforceable.

59. The claims of the '614 patent are directed to a human or humanized, monoclonal anti-CGRP antagonist antibody that preferentially binds to human α-CGRP as compared to amylin.

E. U.S Patent No. 9,346,881

60. On May 24, 2016, United States Patent No. 9,346,881 ("the '881 patent"), titled "Antagonist antibodies directed against calcitonin gene-related peptide and methods using same," issued to Labrys Biologics, Inc. as assignee of the named inventors Joerg Zeller, Kristian T. Poulsen, Yasmina N. Abdiche, Jaume Pons, Sierra Leigh Jones Collier, and Arnon Rosenthal. A copy of the '881 patent is attached as Exhibit 24.

61. A confirmatory assignment of the '881 patent from Labrys to Teva was executed on September 19, 2016. The '881 patent is valid and enforceable.

62. The claims of the '881 patent are directed to a human or humanized, monoclonal anti-CGRP antagonist antibody that binds human α-CGRP and inhibits human α-CGRP from binding to its receptor as measured by a radioligand binding assay in SK-N-MC cells.

F. U.S. Patent No. 9,884,907

63. On February 6, 2018, United States Patent No. 9,884,907 ("the '907 patent"), titled "Methods for treating headache using antagonist antibodies directed against calcitonin gene-related peptide," issued to Teva Pharmaceuticals International GmbH as assignee of the named inventors Joerg Zeller, Kristian T. Poulsen, Yasmina Noubia Abdiche, Jaume Pons, Sierra Jones Collier, and Arnon Rosenthal. A copy of the '907 patent is attached as Exhibit 32.

64. The '907 patent is valid and enforceable.

65. The claims of the '907 patent are directed to a method of treating headache in an individual, comprising administering to the individual an effective amount of 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.

66. The ’907 patent discloses that headache includes migraine.

67. The ’907 patent discloses that SEQ ID NO:15 recites the amino acid sequence of human α-CGRP and SEQ ID NO:43 recites the amino acid sequence of human β-CGRP.

G. U.S. Patent No. 9,884,908

68. On February 6, 2018, United States Patent No. 9,884,908 (“the ’908 patent”), titled “Antagonist antibodies directed against calcitonin gene-related peptide and methods using same,” issued to Teva Pharmaceuticals International GmbH as assignee of the named inventors Joerg Zeller, Kristian T. Poulsen, Yasmina Noubia Abdiche, Jaume Pons, Sierra Jones Collier, and Arnon Rosenthal. A copy of the ’908 patent is attached as Exhibit 33.

69. The ’908 patent is valid and enforceable.

70. The claims of the ’908 patent are directed to a method of treating headache in an individual, comprising: administering to the individual an effective amount of a humanized monoclonal anti-CGRP antagonist antibody, comprising: two human IgG heavy chains, each heavy chain comprising three 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.

71. The ’908 patent discloses that headache includes migraine.

72. The ’908 patent discloses that SEQ ID NO:15 recites the amino acid sequence of human α-CGRP and SEQ ID NO:43 recites the amino acid sequence of human β-CGRP.

H. U.S. Patent No. 9,890,210

73. On February 13, 2018, United States Patent No. 9,890,210 (“the ’210 patent”), titled “Antagonist antibodies directed against calcitonin gene-related peptide,” issued to Teva Pharmaceuticals International GmbH as assignee of the named inventors Joerg Zeller, Kristian T. Poulsen, Yasmina Noubia Abdiche, Jaume Pons, Sierra Jones Collier, and Arnon Rosenthal. A copy of the ’210 patent is attached as Exhibit 34.

74. The ’210 patent is valid and enforceable.

75. The claims of the ’210 patent are directed to a humanized monoclonal anti-CGRP antagonist antibody, comprising: two human IgG heavy chains, each heavy chain comprising three 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.

76. The ’210 patent discloses that SEQ ID NO:15 recites the amino acid sequence of human α-CGRP and SEQ ID NO:43 recites the amino acid sequence of human β-CGRP.

I. U.S. Patent No. 9,890,211

77. On February 13, 2018, United States Patent No. 9,890,211 (“the ’211 patent”), titled “Antagonist antibodies directed against calcitonin gene-related peptide,” issued to Teva Pharmaceuticals International GmbH as assignee of the named inventors Joerg Zeller, Kristian T. Poulsen, Yasmina Noubia Abdiche, Jaume Pons, Sierra Jones Collier, and Arnon Rosenthal. A copy of the ’211 patent is attached as Exhibit 35.

78. The ’211 patent is valid and enforceable.

79. The claims of the ’211 patent are directed to a humanized monoclonal anti-CGRP antagonist antibody, comprising: two human IgG heavy chains, each heavy chain comprising three 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 37°C.

80. The ’211 patent discloses that SEQ ID NO:15 recites the amino acid sequence of human α-CGRP and SEQ ID NO:43 recites the amino acid sequence of human β-CGRP.

DEFENDANT’S INFRINGING CONDUCT

81. On October 24, 2017, Eli Lilly confirmed that it has submitted a BLA requesting approval of its Galcanezumab Product for the prevention of both episodic and chronic migraine.

82. On September 27, 2018, FDA approved Eli Lilly’s BLA, clearing the way for the commercial launch of the Galcanezumab Product under the brand name Emgality™.

83. The Galcanezumab Product contains the humanized monoclonal antibody galcanezumab.

84. Galcanezumab is able to bind to CGRP and inhibit CGRP biological activity and/or downstream pathway(s) mediated by CGRP signaling. *See* Ex. 25 (https://www.lilly.com/pipeline/10.html (last visited on October 24, 2017)); *see also* Ex. 26, Benschop, *et al*., “Development of a novel antibody to calcitonin gene-related peptide for the treatment of osteoarthritis-related pain,” OSTEOARTHRITIS AND CARTILAGE, 22:578-585, 2014 (“Benschop”).

85. Galcanezumab is a humanized monoclonal antibody. Ex. 27, Vermeersch, *et al*., "Translational Pharmacodynamics of Calcitonin Gene-Related Peptide Monoclonal Antibody LY2951742 in Capsaicin-Induced Dermal Blood Flow Model," J. PHARMACOL. EXP. THERA., 354:350-357, September 2015.

86. Galcanezumab binds to human α-CGRP. Ex. 27, Vermeersch at p. 350.

87. Galcanezumab prevents CGRP from binding to its receptor as measured by a radioligand binding assay in SK-N-MC cells. Ex. 26, Benschop at p. 579-81.

88. Galcanezumab has a binding affinity to human CGRP of 31 pM as measured by surface plasmon resonance at 37º C. Ex. 26, Benschop at p. 580.

89. Galcanezumab binds to α- and β-CGRP with approximately equal affinity. Ex. 27, Vermeersch at p. 350.

90. Upon information and belief, galcanezumab decreases the biological activity of the CGRP receptor.

91. Galcanezumab inhibits cAMP activation in cells. Ex. 26, Benschop at p. 581.

92. Galcanezumab preferentially binds to human CGRP as compared to amylin. Ex. 26, Benschop at p. 580.

93. The FDA requires that prescription biologic drugs be labeled and/or sold with package inserts providing information about the drugs and their use, including essential scientific information needed for safe and effective use, indications and usage, and dosage and administration. 21 C.F.R. § 201.50 *et seq.*

94. Eli Lilly will market the Galcanezumab Product with labeling and product information in compliance with FDA requirements.

95. The labelling and/or package insert for the Galcanezumab Product will include instructions for how to use it for the prevention of both episodic and chronic migraine, including

how to administer an effective dose. 21 C.F.R. §§ 201.55, 201.56, 201.57.

96. Eli Lilly will also instruct physicians how to use the Galcanezumab Product for the prevention of both episodic and chronic migraine, including how to administer an effective dose consistent with the FDA-approved instructions.

COUNT I FOR INFRINGEMENT AS TO THE '045 PATENT

97. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-96.

98. Upon information and belief, having received FDA approval, Defendant is currently manufacturing, marketing, selling, offering to sell, promoting, and/or importing the Galcanezumab Product in the United States.

99. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '045 patent.

100. Upon information and belief, Defendant is actively inducing others to infringe the '045 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in the United States in violation of 35 U.S.C. § 271(b). Defendant's inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing patients and/or physicians to use and/or prescribe the Galcanezumab Product in accordance with the FDA-approved label for the Galcanezumab Product.

101. Upon information and belief, Defendant has been and is contributing to the infringement of the '045 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in violation of 35 U.S.C. § 271(c). Upon information and belief, the Galcanezumab Product is not a staple article or commodity of commerce suitable for substantial non-

infringing use.

102. Upon information and belief, Defendant will continue to indirectly infringe the ’045 patent unless enjoined by this Court.

103. Upon information and belief, as a result of Defendant’s indirect infringement of the ’045 patent, Teva has suffered damages.

104. Upon information and belief, Defendant will knowingly and willfully infringe the ’045 patent.

105. This case is exceptional, and Teva is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT AS TO THE ’649 PATENT

106. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-105.

107. Upon information and belief, having received FDA approval, Defendant is currently manufacturing, marketing, selling, offering to sell, promoting, and/or importing the Galcanezumab Product in the United States.

108. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the ’649 patent.

109. Upon information and belief, Defendant is actively inducing others to infringe the ’649 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in the United States in violation of 35 U.S.C. § 271(b). Defendant’s inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing patients and/or physicians to use and/or prescribe the Galcanezumab Product in accordance with the FDA-approved label for the Galcanezumab Product.

110. Upon information and belief, Defendant has been and is contributing to the infringement of the ’649 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in violation of 35 U.S.C. § 271(c). Upon information and belief, the Galcanezumab Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

111. Upon information and belief, Defendant will continue to indirectly infringe the ’649 patent unless enjoined by this Court.

112. Upon information and belief, as a result of Defendant’s indirect infringement of the ’649 patent, Teva has suffered damages.

113. Upon information and belief, Defendant will knowingly and willfully infringe the ’649 patent.

114. This case is exceptional, and Teva is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT AS TO THE ’951 PATENT

115. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-114.

116. Upon information and belief, having received FDA approval, Defendant is currently manufacturing, marketing, selling, offering to sell, promoting, and/or importing the Galcanezumab Product in the United States.

117. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the ’951 patent.

118. Upon information and belief, Defendant is actively inducing others to infringe the ’951 patent in this District and elsewhere in the United States by making, offering to sell,

selling, importing and otherwise promoting and distributing the Galcanezumab Product in the United States in violation of 35 U.S.C. § 271(b). Defendant's inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing patients and/or physicians to use and/or prescribe the Galcanezumab Product in accordance with the FDA-approved label for the Galcanezumab Product.

119. Upon information and belief, Defendant has been and is contributing to the infringement of the '951 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in violation of 35 U.S.C. § 271(c). Upon information and belief, the Galcanezumab Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

120. Upon information and belief, Defendant will continue to indirectly infringe the '951 patent unless enjoined by this Court.

121. Upon information and belief, as a result of Defendant's indirect infringement of the '951 patent, Teva has suffered damages.

122. Upon information and belief, Defendant will knowingly and willfully infringe the '951 patent.

123. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT AS TO THE '614 PATENT

124. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-123.

125. Upon information and belief, having received FDA approval, Defendant is currently manufacturing, marketing, selling, offering to sell, promoting, and/or importing the

Galcanezumab Product in the United States.

126. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the ’614 patent.

127. Upon information and belief, Defendant is actively inducing others to infringe the ’614 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in the United States in violation of 35 U.S.C. § 271(b). Defendant’s inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing patients and/or physicians to use and/or prescribe the Galcanezumab Product in accordance with the FDA-approved label for the Galcanezumab Product.

128. Upon information and belief, Defendant has been and is contributing to the infringement of the ’614 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in violation of 35 U.S.C. § 271(c). Upon information and belief, the Galcanezumab Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

129. Upon information and belief, Defendant will continue to indirectly infringe the ’614 patent unless enjoined by this Court.

130. Upon information and belief, as a result of Defendant’s indirect infringement of the ’614 patent, Teva has suffered damages.

131. Upon information and belief, Defendant will knowingly and willfully infringe the ’614 patent.

132. This case is exceptional, and Teva is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT V FOR INFRINGEMENT AS TO THE '881 PATENT

133. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-132.

134. Upon information and belief, having received FDA approval, Defendant is currently manufacturing, marketing, selling, offering to sell, promoting, and/or importing the Galcanezumab Product in the United States.

135. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '881 patent.

136. Upon information and belief, Defendant is actively inducing others to infringe the '881 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in the United States in violation of 35 U.S.C. § 271(b). Defendant's inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing patients and/or physicians to use and/or prescribe the Galcanezumab Product in accordance with the FDA-approved label for the Galcanezumab Product.

137. Upon information and belief, Defendant has been and is contributing to the infringement of the '881 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in violation of 35 U.S.C. § 271(c). Upon information and belief, the Galcanezumab Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

138. Upon information and belief, Defendant will continue to indirectly infringe the '881 patent unless enjoined by this Court.

139. Upon information and belief, as a result of Defendant's indirect infringement of the '881 patent, Teva has suffered damages.

140. Upon information and belief, Defendant will knowingly and willfully infringe the '881 patent.

141. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VI FOR INFRINGEMENT AS TO THE '907 PATENT

142. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-141.

143. Upon information and belief, having received FDA approval, Defendant is currently manufacturing, marketing, selling, offering to sell, promoting, and/or importing the Galcanezumab Product in the United States.

144. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '907 patent.

145. Upon information and belief, Defendant is actively inducing others to infringe the '907 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in the United States in violation of 35 U.S.C. § 271(b). Defendant's inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing patients and/or physicians to use and/or prescribe the Galcanezumab Product in accordance with the FDA-approved label for the Galcanezumab Product.

146. Upon information and belief, Defendant has been and is contributing to the infringement of the '907 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab

Product in violation of 35 U.S.C. § 271(c). Upon information and belief, the Galcanezumab Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

147. Upon information and belief, Defendant will continue to indirectly infringe the '907 patent unless enjoined by this Court.

148. Upon information and belief, as a result of Defendant's indirect infringement of the '907 patent, Teva has suffered damages.

149. Upon information and belief, Defendant will knowingly and willfully infringe the '907 patent.

150. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VII FOR INFRINGEMENT AS TO THE '908 PATENT

151. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-150.

152. Upon information and belief, having received FDA approval, Defendant is currently manufacturing, marketing, selling, offering to sell, promoting, and/or importing the Galcanezumab Product in the United States.

153. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '908 patent.

154. Upon information and belief, Defendant is actively inducing others to infringe the '908 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in the United States in violation of 35 U.S.C. § 271(b). Defendant's inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing

patients and/or physicians to use and/or prescribe the Galcanezumab Product in accordance with the FDA-approved label for the Galcanezumab Product.

155. Upon information and belief, Defendant has been and is contributing to the infringement of the ’908 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in violation of 35 U.S.C. § 271(c). Upon information and belief, the Galcanezumab Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

156. Upon information and belief, Defendant will continue to indirectly infringe the ’908 patent unless enjoined by this Court.

157. Upon information and belief, as a result of Defendant’s indirect infringement of the ’908 patent, Teva has suffered damages.

158. Upon information and belief, Defendant will knowingly and willfully infringe the ’908 patent.

159. This case is exceptional, and Teva is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT VIII FOR INFRINGEMENT AS TO THE ’210 PATENT

160. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-159.

161. Upon information and belief, having received FDA approval, Defendant is currently manufacturing, marketing, selling, offering to sell, promoting, and/or importing the Galcanezumab Product in the United States.

162. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the ’210 patent.

163. Upon information and belief, Defendant is actively inducing others to infringe the ’210 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in the United States in violation of 35 U.S.C. § 271(b). Defendant’s inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing patients and/or physicians to use and/or prescribe the Galcanezumab Product in accordance with the FDA-approved label for the Galcanezumab Product.

164. Upon information and belief, Defendant has been and is contributing to the infringement of the ’210 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in violation of 35 U.S.C. § 271(c). Upon information and belief, the Galcanezumab Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

165. Upon information and belief, Defendant will continue to indirectly infringe the ’210 patent unless enjoined by this Court.

166. Upon information and belief, as a result of Defendant’s indirect infringement of the ’210 patent, Teva has suffered damages.

167. Upon information and belief, Defendant will knowingly and willfully infringe the ’210 patent.

168. This case is exceptional, and Teva is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT IX FOR INFRINGEMENT AS TO THE ’211 PATENT

169. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-168.

170. Upon information and belief, having received FDA approval, Defendant is currently manufacturing, marketing, selling, offering to sell, promoting, and/or importing the Galcanezumab Product in the United States.

171. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '211 patent.

172. Upon information and belief, Defendant is actively inducing others to infringe the '211 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in the United States in violation of 35 U.S.C. § 271(b). Defendant's inducement includes, without limitation and with specific intent to encourage direct infringement, knowingly inducing patients and/or physicians to use and/or prescribe the Galcanezumab Product in accordance with the FDA-approved label for the Galcanezumab Product.

173. Upon information and belief, Defendant has been and is contributing to the infringement of the '211 patent in this District and elsewhere in the United States by making, offering to sell, selling, importing and otherwise promoting and distributing the Galcanezumab Product in violation of 35 U.S.C. § 271(c). Upon information and belief, the Galcanezumab Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

174. Upon information and belief, Defendant will continue to indirectly infringe the '211 patent unless enjoined by this Court.

175. Upon information and belief, as a result of Defendant's indirect infringement of the '211 patent, Teva has suffered damages.

176. Upon information and belief, Defendant will knowingly and willfully infringe the '211 patent.

177. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT X FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '045 PATENT

178. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-177.

179. Upon information and belief, Defendant intends to manufacture, market, sell, offer to sell, and/or import the Galcanezumab Product immediately upon receiving FDA approval.

180. Defendant's submission of a BLA to the FDA, coupled with Defendant's activities in support of its manufacture, importation, and launch of the Galcanezumab Product for commercial sale in the United States upon receiving that approval, creates an actual, immediate, and real controversy within the Declaratory Judgment Act regarding Defendant's infringement, or active inducement and/or contribution to infringement of, valid and enforceable claims of the '045 patent before its expiration in violation of 35 U.S.C. § 271(a), (b), or (c). Defendant's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendant's imminently infringing activities.

181. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '045 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

182. Upon information and belief, Defendant will knowingly and willfully infringe the '045 patent.

183. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XI FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '649 PATENT

184. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-183.

185. Upon information and belief, Defendant intends to manufacture, market, sell, offer to sell and/or import the Galcanezumab Product immediately upon receiving the FDA approval.

186. Defendant's submission of a BLA to the FDA, coupled with Defendant's activities in support of its manufacture, importation, and launch of the Galcanezumab Product for commercial sale in the United States upon receiving that approval, creates an actual, immediate, and real controversy within the Declaratory Judgment Act regarding Defendant's direct infringement, or active inducement and/or contribution to infringement of, valid and enforceable claims of the '649 patent before its expiration in violation of 35 U.S.C. § 271(a), (b), or (c). Defendant's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendant's imminently infringing activities.

187. Galcanezumab and/or its manufacture satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '649 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

188. Upon information and belief, Defendant will knowingly and willfully infringe the '649 patent.

189. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XII FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '951 PATENT

190. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-189.

191. Upon information and belief, Defendant intends to manufacture, market,

sell, offer to sell and/or import the Galcanezumab Product immediately upon receiving FDA approval.

192. Defendant's submission of a BLA to the FDA, coupled with Defendant's activities in support of its manufacture, importation, and launch of the Galcanezumab Product for commercial sale in the United States upon receiving that approval, creates an actual, immediate, and real controversy within the Declaratory Judgment Act regarding Defendant's direct infringement, or active inducement and/or contribution to infringement of, valid and enforceable claims of the '951 patent before its expiration in violation of 35 U.S.C. § 271(a), (b), or (c). Defendant's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendant's imminently infringing activities.

193. Galcanezumab and/or its manufacture satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '951 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

194. Upon information and belief, Defendant will knowingly and willfully infringe the '951 patent.

195. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '614 PATENT

196. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-195.

197. Upon information and belief, Defendant intends to manufacture, market, sell, offer to sell and/or import the Galcanezumab Product immediately upon receiving FDA approval.

198. Defendant's submission of a BLA to the FDA, coupled with Defendant's

activities in support of its manufacture, importation, and launch of the Galcanezumab Product for commercial sale in the United States upon receiving that approval, creates an actual, immediate, and real controversy within the Declaratory Judgment Act regarding Defendant's direct infringement, or active inducement and/or contribution to infringement of, valid and enforceable claims of the '614 patent before its expiration in violation of 35 U.S.C. § 271(a), (b), or (c). Defendant's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendant's imminently infringing activities.

199. The Galcanezumab Product and/or its manufacture satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '614 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

200. Upon information and belief, Defendant will knowingly and willfully infringe the '614 patent.

201. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XIV FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '881 PATENT

202. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-201.

203. Upon information and belief, Defendant intends to manufacture, market, sell, offer to sell and/or import the Galcanezumab Product immediately upon receiving FDA approval.

204. Defendant's submission of a BLA to the FDA, coupled with Defendant's activities in support of its manufacture, importation, and launch of the Galcanezumab Product for commercial sale in the United States upon receiving that approval, creates an actual,

immediate, and real controversy within the Declaratory Judgment Act regarding Defendant's direct infringement, or active inducement and/or contribution to infringement of, valid and enforceable claims of the '881 patent before its expiration in violation of 35 U.S.C. § 271(a), (b), or (c). Defendant's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendant's imminently infringing activities.

205. The Galcanezumab Product and/or its manufacture satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '881 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

206. Upon information and belief, Defendant will knowingly and willfully infringe the '881 patent.

207. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XV FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '907 PATENT

208. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-207.

209. Upon information and belief, Defendant intends to manufacture, market, sell, offer to sell, and/or import the Galcanezumab Product immediately upon receiving FDA approval.

210. Defendant's submission of a BLA to the FDA, and acceptance by the FDA, coupled with Defendant's activities in support of its manufacture, importation, and launch of the Galcanezumab Product for commercial sale in the United States upon receiving that approval, creates an actual, immediate, and real controversy within the Declaratory Judgment Act regarding Defendant's infringement, or active inducement and/or contribution to

infringement of, valid and enforceable claims of the ’907 patent before its expiration in violation of 35 U.S.C. § 271(a), (b), or (c). Defendant’s actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendant’s imminently infringing activities.

211. The Galcanezumab Product and/or its use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the ’907 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

212. Upon information and belief, Defendant will knowingly and willfully infringe the ’907 patent.

213. This case is exceptional, and Teva is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT XVI FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE ’908 PATENT

214. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-213.

215. Upon information and belief, Defendant intends to manufacture, market, sell, offer to sell and/or import the Galcanezumab Product immediately upon receiving FDA approval.

216. Defendant’s submission of a BLA to the FDA, and acceptance by the FDA, coupled with Defendant’s activities in support of its manufacture, importation, and launch of the Galcanezumab Product for commercial sale in the United States upon receiving that approval, creates an actual, immediate, and real controversy within the Declaratory Judgment Act regarding Defendant’s direct infringement, or active inducement and/or contribution to infringement of, valid and enforceable claims of the ’908 patent before its expiration in

violation of 35 U.S.C. § 271(a), (b), or (c). Defendant's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendant's imminently infringing activities.

217. Galcanezumab and/or its manufacture satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '908 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

218. Upon information and belief, Defendant will knowingly and willfully infringe the '908 patent.

219. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XVII FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '210 PATENT

220. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-219.

221. Upon information and belief, Defendant intends to manufacture, market, sell, offer to sell and/or import the Galcanezumab Product immediately upon receiving FDA approval.

222. Defendant's submission of a BLA to the FDA, and acceptance by the FDA, coupled with Defendant's activities in support of its manufacture, importation, and launch of the Galcanezumab Product for commercial sale in the United States upon receiving that approval, creates an actual, immediate, and real controversy within the Declaratory Judgment Act regarding Defendant's direct infringement, or active inducement and/or contribution to infringement of, valid and enforceable claims of the '210 patent before its expiration in violation of 35 U.S.C. § 271(a), (b), or (c). Defendant's actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendant's imminently

infringing activities.

223. Galcanezumab and/or its manufacture satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the ’210 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

224. Upon information and belief, Defendant will knowingly and willfully infringe the ’210 patent.

225. This case is exceptional, and Teva is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT XVIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE ’211 PATENT

226. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-225.

227. Upon information and belief, Defendant intends to manufacture, market, sell, offer to sell and/or import the Galcanezumab Product immediately upon receiving FDA approval.

228. Defendant’s submission of a BLA to the FDA, and acceptance by the FDA, coupled with Defendant’s activities in support of its manufacture, importation, and launch of the Galcanezumab Product for commercial sale in the United States upon receiving that approval, creates an actual, immediate, and real controversy within the Declaratory Judgment Act regarding Defendant’s direct infringement, or active inducement and/or contribution to infringement of, valid and enforceable claims of the ’211 patent before its expiration in violation of 35 U.S.C. § 271(a), (b), or (c). Defendant’s actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendant’s imminently infringing activities.

229. Galcanezumab and/or its manufacture satisfies each element and infringes,

either literally or under the doctrine of equivalents, one or more claims of the '211 patent. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

230. Upon information and belief, Defendant will knowingly and willfully infringe the '211 patent.

231. This case is exceptional, and Teva is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Teva prays for judgment against Defendant Eli Lilly and Company and respectfully requests the following relief:

A. A judgment that Eli Lilly's commercial manufacture and launch of its Galcanezumab Product upon FDA approval of its BLA will infringe each of the Patents-in-Suit,

B. Any available injunctive relief to prevent the commercial manufacture, use, offer to sell, or sale of the Galcanezumab Product pursuant to 35 U.S.C. § 283, 28 U.S.C. § 2202, and FED. R. CIV. P. 65;

C. Any available damages pursuant to 35 U.S.C. § 284;

D. A judgment that this is an exceptional case and that Plaintiffs be awarded their attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

F. Such other and further relief as the Court deems just and appropriate.

G. Teva demands a jury for all claims so triable.

Dated: September 27, 2018

Respectfully submitted,

/s/ Douglas J. Kline
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