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

Plaintiffs Teva Pharmaceuticals International GmbH ("Teva GmbH") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Plaintiffs" or "Teva") bring this action for a 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. 9,884,907 and 9,884,908 ("the Patents-in-Suit"). On September 19, 2016, Labrys assigned to Teva patents that claim priority to applications to which the Patents-in-Suit also claim priority. 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. Upon approval, Teva Pharmaceuticals USA, Inc. will be the exclusive distributor of Teva's fremanezumab product.

5. Upon information and belief, Eli Lilly is aware that Teva has patents covering the technology claimed in the Patents-in-Suit, but nonetheless is seeking to launch 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 has submitted its own BLA for the Galcanezumab Product.

Ex. 1 at 3. Through its public statements and commercial activity, Eli Lilly has made clear that it intends to enter the market with its Galcanezumab Product as soon as it receives FDA approval.

6. Eli Lilly's imminent commercial manufacture, importation, offers to sell, and sales of its Galcanezumab Product will directly infringe, or will actively induce and/or contribute to infringement of, claims of each of the Patents-in-Suit. Teva files this action to secure a judicial declaration that Eli Lilly will infringe the Patents-in-Suit and to prevent Eli Lilly from any future infringement.

THE PARTIES

7. 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 owns the Patents-in-Suit.

8. 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.

9. 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

10. 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.

11. 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.

12. 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). In the alternative, 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 plans imminently to commit acts of infringement in the Commonwealth upon FDA approval of Eli Lilly's Galcanezumab Product.

A. Eli Lilly Plans To Launch Its Galcanezumab Product Imminently.

13. 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 has engaged in extensive preparations to bring its Galcanezumab Product to market in the immediate future, including most recently by submitting a BLA to the FDA for approval to market and sell the Galcanezumab Product for the prevention of both episodic and chronic migraine. Eli Lilly announced on December 11, 2017 that its BLA was accepted for review by the FDA. Ex. 2 at 1.

14. Over the course of the past year, Eli Lilly has made many public statements representing that it expects to receive FDA approval of its Galcanezumab Product and indicating that it plans to commercially launch the Galcanezumab Product as soon as the FDA approves its BLA.

15. 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 has submitted a BLA with the FDA to market and sell the Galcanezumab Product for the prevention of both episodic and chronic migraine. This filing signals a serious commitment by Eli Lilly to imminently launch the Galcanezumab Product, because filing a BLA represents a substantial undertaking and investment.

16. Eli Lilly publicly has expressed confidence that the FDA will 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. 3 at 19-20; Ex. 4 at 6. 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. 5 at 38. In its January 31, 2018 Earnings call, Eli Lilly stated that it expects regulatory action for the Galcanezumab Product in 2018. Ex. 6 at 7.

17. Eli Lilly publicly confirmed that it has 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. 7 at 20, 21.

18. Eli Lilly's expectation that it will receive FDA approval to market the Galcanezumab Product in the very near future is 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. 8 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. 9 at 4; Ex. 10 at 4.

B. Eli Lilly Is Actively Preparing To Market And Sell The Galcanezumab Product.

19. Upon information and belief, Eli Lilly will bring the Galcanezumab Product to market as soon as it receives FDA approval. Eli Lilly's preparations to market and sell the Galcanezumab product are already underway. For example, Eli Lilly has instituted substantial

marketing efforts directed at healthcare providers to raise awareness of migraine treatment, is developing education materials about migraine, and is building 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 is engaged in these efforts in the United States generally and in Massachusetts specifically.

20. Eli Lilly has 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. 11 at 1 ("Lilly Migraine U.S. @LillyMigraine," TWITTER, https://twitter.com/lillymigraine (last visited Feb. 6, 2018)). Eli Lilly also created a website, www.uncovermigraine.com, which it has re-launched as www.reframemigraine.com. Eli Lilly has promoted this website at least through its Twitter account and at the 2017 Eighteenth Congress of the International Headache Society. The home screen on the "reframemigraine" website specifically talks about migraine treatments and the "research linking CGRP and migraine." *See* Ex. 12 at 4 ("Is There a Need to Reassess Migraine Management?," LILLY, http://www.reframemigraine.com (last visited Feb. 6, 2018)).

21. As of October 2017, Eli Lilly was actively building a sales force to support the launch of its Galcanezumab Product. Eli Lilly's job board listed open positions for twenty-five sales representative positions who will 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. 13 at 2.

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

22. 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.

23. 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. 14. 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. On December 12, 2017, Eli Lilly also initiated a revocation proceeding against Teva's patent, European Patent (U.K.) No. 1957106 B1. Ex. 15.

24. 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. 14 at 2. All of the Patents-in-Suit also claim priority to the '623 application. In February 2017, the European Patent Office found that EP 1957106 is entitled to the priority date of the '623 application. Ex. 16 at 96-98.

25. Upon information and belief, Eli Lilly pressed ahead with its BLA filing even though it knows that its Galcanezumab product infringes Teva's patents. 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. 17 at 10-11.

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

26. 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.

27. 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. 18 at 1.

28. 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.

29. 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. 18 at 2.

30. Eli Lilly has dozens of pharmaceutical drug products that it currently markets, sells, and distributes in Massachusetts. *See* Ex. 19 ("Products," ELI LILLY AND COMPANY, https://www.lilly.com/products (last visited Feb. 6, 2018)).

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

32. Eli Lilly has carried out Clinical Trials in Massachusetts for the use of the Galcanezumab Product in treatment of migraine, including two Phase 2 studies and three Phase 3 studies. *See* Ex. 20 at 7; Ex. 21 at 6; Ex. 22 at 6. Positive data from these Phase 3 studies (EVOLVE-1, EVOLVE-2 and REGAIN) were included in Eli Lilly's BLA for the Galcanezumab Product. Ex. 2 at 1.

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

33. As of February 6, 2018, 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. 23 at 1.

34. 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.

35. 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. 24 (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).

36. 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. 25.

37. 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.

38. 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.*

39. Eli Lilly's Galcanezumab Product is a biologic product that will be 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. 9,884,907

40. 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 26.

41. The '907 patent is valid and enforceable.

42. 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-Calcitonin Gene-Related Peptide (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 lights 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.

43. The '907 patent discloses that headache includes migraine.

44. 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.

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

45. 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 27.

46. The '908 patent is valid and enforceable.

47. 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-Calcitonin Gene-Related Peptide (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, 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.

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

49. 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.

DEFENDANT’S INFRINGING CONDUCT

50. 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. Ex. 1 at 3.

51. On December 11, 2017, Eli Lilly announced that the FDA has accepted its BLA to review the Galcanezumab Product for the prevention of episodic and chronic migraine. Ex. 2.

52. Eli Lilly’s Galcanezumab Product is an antibody that is able to bind to CGRP and inhibit CGRP biological activity and/or downstream pathway(s) mediated by CGRP signaling. *See* Ex. 28 (https://www.lilly.com/discovery/pipeline (last visited Feb. 6, 2018)); *see also* Ex. 29, 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”).

53. Eli Lilly's Galcanezumab Product is a humanized monoclonal antibody. Ex. 30, 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.

54. Eli Lilly's Galcanezumab Product binds to human α-CGRP. Ex. 30, Vermeersch at p. 350.

55. Eli Lilly's Galcanezumab Product has a binding affinity to human CGRP of 31 pM as measured by surface plasmon resonance at 37º C. Ex. 29, Benschop at p. 580.

56. Eli Lilly's Galcanezumab Product binds to α- and β-CGRP with approximately equal affinity. Ex. 30, Vermeersch at p. 350.

57. Eli Lilly's Galcanezumab Product contains two human IgG heavy chains. Ex. 29, Benschop at p. 579; *See* Ex. 31, Statement on a Nonproprietary Name Adopted by the USAN Council for galcanezumab, August 26, 2015.

58. Each heavy chain of Eli Lilly's Galcanezumab Product contains three complementarity determining regions (CDRs). *See* Ex. 31.

59. Each heavy chain of Eli Lilly's Galcanezumab Product contains four framework regions. *See* Ex. 31.

60. Portions of the two heavy chains of Eli Lilly's Galcanezumab Product together form an Fc region. *See* Ex. 31.

61. Eli Lilly's Galcanezumab Product contains two light chains. *See* Ex. 31.

62. Each light chain of Eli Lilly's Galcanezumab Product contains three CDRs and four framework regions. *See* Ex. 31.

63. The CDRs of Eli Lilly's Galcanezumab Product impart to the antibody specific binding to human α-CGRP and human β-CGRP. Ex. 30, Vermeersch at p. 350.

64. 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.*

65. Upon obtaining approval for Eli Lilly's BLA, Eli Lilly will market its Galcanezumab Product with labeling and product information in compliance with FDA requirements.

66. The labelling and/or package insert for Eli Lilly's Galcanezumab Product will include instructions for how to use the Galcanezumab Product 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.

67. Once the FDA approves Eli Lilly's BLA, 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 DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '907 PATENT

68. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-67.

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

70. 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.

71. 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.

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

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

COUNT II FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '908 PATENT

74. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-73.

75. 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.

76. 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.

77. 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.

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

79. 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: February 6, 2018

Respectfully submitted,

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