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. 1:21-cv-10954

COMPLAINT

Plaintiffs Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. ("Plaintiffs" or "Teva") brings 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. Patients can suffer from episodic migraine, in which migraine occurs on up to 14 days out of a month, or chronic migraine, in which patients suffer from migraine even more frequently. In the United States and Western Europe, over 10% of the

general population suffers from migraine.

3. Migraine patients may receive preventive treatment (intended to be taken before the onset of migraine in order to limit the number or severity of migraines), which can be used alone or in combination with acute treatment (intended to be taken during or after the onset of migraine to limit its severity). Although scientific literature suggests that patients experiencing migraine with some amount of impairment on at least four days per month should receive preventive migraine treatment, only a small fraction of migraine sufferers meeting this definition actually receive preventive treatment.

4. Furthermore, many commonly-prescribed migraine prevention treatments were not developed specifically for the treatment of migraine. As many as 73% of patients treated with these standard-of-care preventives (antidepressant, anti-epileptic, or beta blocker drugs) discontinue treatment within six months. Patients commonly give up on such treatment because of lack of efficacy or intolerable side effects. More than half of chronic migraine patients and more than a quarter of episodic migraine patients switch or discontinue preventive treatment at least once.

5. 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. 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 September 14, 2018, FDA approved Teva's fremanezumab product, known as AJOVY, which launched the same month. On January 28, 2020, FDA approved an autoinjector device for AJOVY ("AJOVY Autoinjector"), and on April 27, 2020, Teva launched the AJOVY Autoinjector. Teva Pharmaceuticals USA, Inc. is the exclusive distributor of AJOVY prefilled syringes and the AJOVY Autoinjector.

6. AJOVY has been shown to prevent and/or reduce the incidence of migraines and was approved by the FDA for this use. AJOVY is one of the first FDA-approved products that was developed specifically for prevention of migraine, and has the potential to help tens of millions of migraine sufferers in the United States.

7. In addition to the work to develop and launch AJOVY for preventive migraine treatment, Teva scientists made the unexpected discovery that antibody drugs like AJOVY that bind to CGRP can be used to help difficult to treat, "refractory" migraine patients, including those who have failed for efficacy, tolerability, or safety reasons on at least two prior preventive treatments or classes of preventive treatments.

8. This innovation is protected by at least U.S. Patent Nos. 11,028,160 and 11,028,161 (respectively, "the '160 patent" and "the '161 patent") (together, "the Patents-in-Suit"). The applications that issued as the Patents-in-Suit were assigned to Teva on January 14, 2021.

9. Upon information and belief, Eli Lilly is aware of the Patents-in-Suit, but nonetheless has marketed its own competing biologic product with the active ingredient galcanezumab, an antibody that targets CGRP, for the treatment of refractory migraine patients.

10. On September 27, 2018, FDA approved Eli Lilly's BLA for its galcanezumab product. This product, known as EMGALITY, is marketed by Eli Lilly for the preventive treatment of refractory migraine patients, and undermines the value of Teva's substantial investment in the Patents-in-Suit. Like Teva's AJOVY, EMGALITY is an antibody that binds to CGRP and is FDA approved as a preventive migraine treatment. Eli Lilly markets and promotes EMGALITY for such use in refractory patients.

11. Upon information and belief, EMGALITY is prescribed in the U.S. by doctors as a preventive treatment for refractory migraine patients, as claimed by the Patents-in-Suit. Upon information and belief, Eli Lilly is aware that doctors in the U.S. practice the method of treatment claimed by the Patents-in-Suit by selecting migraine patients who previously failed at least two prior preventive treatments or classes of treatment and treating these patients with EMGALITY.

12. Eli Lilly's promotion and marketing of EMGALITY actively induces these doctors to infringe claims of each of the Patents-in-Suit. Teva files this action to secure a judicial declaration that Eli Lilly's activities actively induce infringement of the Patents-in-Suit and to prevent Eli Lilly from any future infringement. Teva also files this action to obtain redress for Eli Lilly's continued active inducement of the Patents-in-Suit.

THE PARTIES

13. Teva Pharmaceuticals International 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 Pharmaceuticals International GmbH owns the Patents-in- Suit.

14. Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway,

Parsippany, NJ 07054. Teva Pharmaceuticals USA, Inc. holds the Biologics License Application (BLA) for AJOVY and is responsible for marketing AJOVY in the U.S.

15. 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

16. 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.

17. 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.

18. 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 actively induces infringement of the Patents-in-Suit in the Commonwealth.

A. Eli Lilly Has Launched EMGALITY

19. On information and belief, shortly after EMGALITY received FDA approval for preventive migraine treatment on September 27, 2018, Eli Lilly launched EMGALITY for sale in the United States. Ex. 3 ("Lilly's Emgality™ (galcanezumab-gnlm) Receives U.S. FDA Approval for the Preventive Treatment of Migraine in Adults," ELI LILLY (Sept. 27, 2018)) ("Emgality will be available to patients shortly after approval.").

20. There is an actual controversy regarding Eli Lilly's active inducement of infringement of the Patents-in-Suit by marketing and promoting EMGALITY for use according

to the patented method. Eli Lilly is engaged in these efforts in the United States generally and in Massachusetts specifically.

B. Eli Lilly Is Actively Marketing And Selling EMGALITY

21. Eli Lilly is actively marketing and selling EMGALITY, and is engaged in this activity in the United States and Massachusetts. Eli Lilly has instituted substantial marketing efforts directed at healthcare providers to raise awareness of refractory migraine treatment, has developed education materials about refractory migraine, and has built a sales force for EMGALITY.

22. 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 refractory migraine. For example, Eli Lilly has established a website for EMGALITY, where it markets EMGALITY both to consumers and healthcare providers ("HCP") using the www.emgality.com web domain ("the EMGALITY website"). *See* Ex. 4 ("Preventive Migraine Treatment | Emgality® (galcanezumab-gnlm)," ELI LILLY, http://www.emgality.com/hcp (last visited June 8, 2021)); Ex. 5 ("For Healthcare Professionals | Emgality® (galcanezumab-gnlm)," ELI LILLY, http://www.emgality.com/hcp (last visited June 8, 2021)). The EMGALITY website bears Eli Lilly's logo and includes a link to "Contact Lilly." *Id.*

23. On the EMGALITY website, Eli Lilly provides specific links and information for healthcare providers. Ex. 5 ("For Healthcare Professionals | Emgality® (galcanezumab-gnlm)," ELI LILLY, http://www.emgality.com/hcp (last visited June 8, 2021)). The healthcare provider page specifically references the use of EMGALITY for patients with refractory episodic or chronic migraine, who have previously been treated with other preventative migraine drugs. *Id.*

24. And Eli Lilly invites healthcare providers to request samples of EMGALITY, and

to contact Lilly via phone, Facebook, and Twitter for information regarding EMGALITY. Ex. 6 ("EMGALITY® (galcanezumab-gnlm): Samples," LILLY MEDICAL, https://www.lillymedical.com/en-us/answers/emgality-galcanezumab-gnlm-samples-86523 (last visited June 8, 2021)).

25. Eli Lilly also maintains a sales force to market EMGALITY. Healthcare providers can request a sales representative visit for EMGALITY via the Eli Lilly website. Ex. 7 ("EMGALITY® (galcanezumab-gnlm): Sales Rep," LILLY MEDICAL, https://www.lillymedical.com/en-us/answers/emgality-galcanezumab-gnlm-sales-rep-86522 (last visited June 8, 2021)).

C. Eli Lilly Knows or Should Know About 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 believes that Eli Lilly knows about the Patents-in-Suit and that the marketing and promotion of EMGALITY for treatment of refractory migraine patients in the United States infringes the claims of the Patents-in-Suit.

27. Upon information and belief, Eli Lilly knows of the existence of U.S. Patent Application Nos. 17/076,772 and 17/076,759 (respectively, "the '772 application" and "the '759 application").

28. The '772 and '759 applications issued as the Patents-in-Suit on June 8, 2021.

29. Upon information and belief, Eli Lilly knows that the U.S. Patent and Trademark Office ("USPTO") issued a Notice of Allowance for the claims of the '772 and '759 applications on March 31, 2021.

30. The USPTO's March 31, 2021 Notice of Allowance for the claims of the '772 and '759 applications is publicly available via the Internet on the USPTO's public Patent Application Information Retrieval ("PAIR") database.

31. Upon information and belief, Eli Lilly knows that a transmittal letter was submitted to the USPTO on May 5, 2021 indicating that Teva was paying the issue fee for the '772 and '759 applications.

32. Teva's May 5, 2021 transmittal letter for the '772 and '759 application issue fees is publicly available via the Internet on the USPTO's public PAIR database.

33. Upon information and belief, Eli Lilly knows that Issue Notifications for the '772 and '759 applications were issued by the USPTO on May 19, 2021.

34. The USPTO's May 19, 2021 Issue Notifications for the '772 and '759 applications is publicly available via the Internet on the USPTO's public PAIR database.

35. The USPTO's May 19, 2021 Issue Notifications for the '772 and '759 applications indicate an issue date of June 8, 2021 for the Patents-in-Suit.

36. In 2018, Teva filed suit in this district against Eli Lilly for infringement of other Teva patents protecting Teva's anti-CGRP antibody intellectual property ("the First EMGALITY Suit"). *See* Complaint, *Teva Pharms. Int'l GmbH et al. v. Eli Lilly and Co*., No. 1:18-cv-12029 (D. Mass. Sept. 27, 2018) (ECF No. 1). The patents asserted by Teva in the First EMGALITY Suit claim compositions of matter and methods of treatment that are also infringed by Eli Lilly's EMGALITY product. *Id.*

37. Upon information and belief, Eli Lilly is familiar with the prosecution at the USPTO of Teva's anti-CGRP antibody intellectual property, including based on its participation in the First EMGALITY Suit.

38. In the First Emgality Suit, Eli Lilly served a May 5, 2021 notice of deposition for Marcelo Bigal, a named inventor on the Patents-in-Suit. Ex. 8 (Notice of Deposition of Marcelo Bigal). Dr. Bigal's deposition is scheduled for June 10, 2021 in the First EMGALITY Suit.

39. Upon information and belief, Eli Lilly knows about the Patents-in-Suit at least in connection with its preparation for Dr. Bigal's imminent deposition in the First EMGALITY Suit.

40. Eli Lilly also knows about the family of patents and applications claiming priority to U.S. Provisional Application Nos. 62/399,180 and 62/558,557 (respectively, "the '180 provisional" and "the '557 provisional"), to which the Patents-in-Suit belong.

41. Eli Lilly has sought discovery from Teva regarding this patent family in the First EMGALITY Suit, specifically referring to the '180 provisional and/or the '557 provisional. Eli Lilly issued a deposition notice to Teva in the First EMGALITY Suit pursuant to Federal Rule of Civil Procedure 30(b)(6). That deposition notice requested testimony from corporate representatives of Teva regarding "[t]he research, development, and/or testing of each alleged invention claimed or disclosed in U.S. patents and/or patent applications relating to antibodies targeting CGRP or the CGRP pathway assigned to Teva or that Teva had or has an option to license, including . . . U.S. Provisional Application Nos. 62/399,180 and 62/558,557, . . . and their Counterparts" and regarding "[t]he preparation, filing, and prosecution of U.S. patents and/or patent applications relating to antibodies targeting CGRP or the CGRP pathway currently assigned to Teva or that Teva had or has an option to license, including . . . U.S. Provisional Application Nos. 62/399,180 and 62/558,557, . . . and their Counterparts." Ex. 9 at Topics 11 & 22 (Excerpt of Eli Lilly Notice of Deposition of Teva Pursuant to Fed. R. Civ. P. 30(b)(6)).[1]

42. Both the published '772 and '759 applications that issued as the Patents-in-Suit claim priority to the '180 and '557 provisionals on their face. Ex 10 (published '772

[1] The 30(b)(6) notice is marked Highly Confidential, but Eli Lilly has confirmed it contains no Eli Lilly highly confidential information.

application); Ex. 11 (published ’759 application). The ’772 and ’759 applications both published on February 11, 2021. *Id.* Eli Lilly issued its 30(b)(6) deposition notice to Teva in the First EMGALITY Suit, which identified the ’180 and ’557 provisionals as subjects for testimony, on March 8, 2021.

43. The “child continuity data” section of the public PAIR database identifies patent and applications related to the selected patent or application by a claim of priority. The public PAIR database entries for each of the ’180 and ’557 provisionals includes a “child continuity data” section identifying each of ’772 and ’759 applications that issued as the Patents-in-Suit as one that “claims the benefit” of the provisionals. Ex. 12 (public PAIR child continuity data entry for ’180 provisional); Ex. 13 (public PAIR child continuity data entry for ’557 provisional)

44. Eli Lilly also knows about the other issued United States patent in the same family as the Patents-in-Suit, U.S. Patent No. 10,392,434 (“the ’434 patent”). On their face, both of the Patents-in-Suit claim priority to the ’434 patent. Exs 1, 2. And like the Patents-in-Suit, on its face the ’434 patent also claims priority to the ’180 and ’557 provisionals. Ex. 14 (’434 patent).

45. Eli Lilly has identified the ’434 patent, and statements made during prosecution of the application that issued as the ’434 patent before the USPTO, in Eli Lilly’s invalidity contentions in the First EMGALITY Suit. Ex. 15 (Excerpt of Eli Lilly Invalidity Contentions).[2]

46. Upon information and belief, Eli Lilly knows or should know about the existence of the Patents-in-Suit based on at least its active monitoring of Teva’s intellectual property for

[2] The contentions are marked Highly Confidential, but in relevant part contain only public Teva information.

anti-CGRP antibodies for migraine treatment, including Teva's U.S. patent portfolio and prosecution activities.

47. Upon information and belief, Eli Lilly knew or should have known that the Patents-in-Suit would issue on June 8, 2021, pursuant to the May 19, 2021 Issue Notifications.

48. Upon information and belief, Eli Lilly knows or should have known of the issuance of the Patents-in-Suit on June 8, 2021.

49. Upon information and belief, despite Eli Lilly's knowledge of the imminent issuance of the Patents-in-Suit, Eli Lilly has deliberately continued to promote EMGALITY for the treatment of refractory migraine patients as described herein.

50. Eli Lilly has actual knowledge of the Patents-in-Suit at least as of the date of service of this Complaint.

51. Upon information and belief, Eli Lilly will continue its activities that encourage doctors to prescribe EMGALITY for the treatment of refractory migraine patients after the date of service of this Complaint.

D. Eli Lilly Has A Substantial And Continuous Presence In This Judicial District And Is Committing Acts Of Infringement In Massachusetts.

52. 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.

53. 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. 16.

54. 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.

55. In its March 12, 2021 Annual Report filed with Massachusetts, Eli Lilly described its business in the Commonwealth as pharmaceutical manufacturing. *Id*.

56. Eli Lilly has dozens of pharmaceutical drug products that it currently markets, sells, and distributes in Massachusetts. *See* Ex. 17 ("Current Medicines," ELI LILLY AND COMPANY, https://www.lilly.com/our-medicines/current-medicines (last visited June 8, 2021)).

57. Eli Lilly also employs consultants and salespeople in Massachusetts to work with Massachusetts healthcare providers.

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

58. As of June 8, 2021, 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. 18 ("Contact Us," Eli Lilly, https://www.lilly.com/contact-us (last visited June 8, 2021).

59. The Cambridge, Massachusetts address is home to Eli Lilly's "Cambridge Innovation Center" ("Innovation Center"). *See* Ex. 19 ("Eli Lilly and Company Reveals Plan for Innovation Center in Cambridge, Massachusetts," ELI LILLY (May 6, 2015)). The Innovation Center serves as a location for the company's research and development efforts with respect to drug delivery and device innovation. *Id.* This Innovation Center includes research into

treatments for pain and biologics that require injections. *Id.*

60. 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. 20 (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 (last visited June 8, 2021).

61. 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. *See* Ex. 19 ("Eli Lilly and Company Reveals Plan for Innovation Center in Cambridge, Massachusetts," ELI LILLY (May 6, 2015)).

62. 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." *Id.*

63. 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.*

64. Eli Lilly's EMGALITY is a biologic product that is administered by injection, including using a pen autoinjector device and, upon information and belief, is part of the Innovation Center's mandate. *See* Ex. 21 (Wil Dubois, "Inside the Lilly Cambridge Innovation

Center and Their 'Connected Diabetes Ecosystem," HEALTHLINE (June 1, 2018), https://www.healthline.com/diabetesmine/lilly-diabetes-blogger-summit-2018#1) ("Lilly's Innovation operation is located on the third and fourth floors of a modern but otherwise nondescript office building at 450 Kendall Street, on the cusp of the MIT campus. . . . A large part of the center's work centers on devices in the broadest possible sense, ranging from simple pills packs to high-tech auto injectors for the full range of Lilly pharmaceutical products.").

THE PATENTS-IN-SUIT

A. U.S. Patent No. 11,028,160

65. On June 8, 2021, United States Patent No. 11,028,160 ("the '160 patent"), titled "Treating Refractory Migraine," issued to Teva Pharmaceuticals International GmbH as assignee of the named inventors Marcelo Bigal and Ernesto Aycardi. A copy of the '160 patent is attached as Exhibit 47.

66. The claims of the '160 patent are directed to methods for treating or preventing migraine in a subject having refractory migraine, comprising administering to the individual a human or humanized anti-CGRP antagonist antibody.

67. The '160 patent is valid and enforceable.

B. U.S. Patent No. 11,028,161

68. On June 8, 2021, United States Patent No. 11,028,161 ("the '161 patent"), titled "Treating Refractory Migraine," issued to Teva Pharmaceuticals International GmbH as assignee of the named inventors Marcelo Bigal and Ernesto Aycardi. A copy of the '161 patent is attached as Exhibit 48.

69. The claims of the '161 patent are directed to methods for treating or preventing migraine in a subject having refractory migraine, comprising administering to the individual a human or humanized anti-CGRP antagonist antibody.

70. The ’161 patent is valid and enforceable.

ELI LILLY’S ACTIVE INDUCEMENT OF INFRINGEMENT

71. On October 24, 2017, Eli Lilly confirmed that it has submitted a BLA requesting approval of EMGALITY for the prevention of both episodic and chronic migraine. On September 27, 2018, FDA approved EMGALITY for the preventive treatment of migraine.

A. EMGALITY Active Ingredient, Formulation, Dosage, and Administration

72. Galcanezumab, the active ingredient in Eli Lilly’s EMGALITY, is an antibody that is able to bind to CGRP and block the binding of CGRP to its receptor. *See* Ex. 22 (“CGRP Antagonist | How Emgality Works,” ELI LILLY, https://www.emgality.com/what-is-emgality/how-it-works (last visited June 8, 2021)); *see also* Ex. 23, 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.

73. EMGALITY is a humanized monoclonal antibody. Ex. 1, 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.

74. Upon information and belief, the amino acid sequence for galcanezumab, the active ingredient in EMGALITY, is disclosed as “antibody III” in Eli Lilly’s U.S. Patent No. 9,505,838 (“the ’838 patent”). Ex. 24 (’838 patent). The amino acid sequences for “antibody III” in Eli Lilly’s ’838 patent correspond to the galcanezumab amino acid sequences published in the FDA “Product Quality Review” for EMGALITY. Ex. 25 (EMGALITY Product Quality Review). Eli Lilly submitted a Patent Term Extension application to the USPTO, requesting that the term of the ’838 patent be extended in view of the regulatory review period for EMGALITY. Ex. 26 (Patent Term Extension Application for ’838 patent).

75. Upon information and belief, the light chain variable region for galcanezumab is SEQ ID NO:19 in the ’838 patent and the heavy chain variable region for galcanezumab is SEQ ID NO:24 in the ’838 patent. SEQ ID NOs:19 and 24 in the ’838 patent correspond to SEQ ID NOs:62 and 63, respectively, of the Patents-in-Suit.

76. Upon information and belief, the amino acid sequence for the light chain variable region of galcanezumab corresponds to SEQ ID NO:62 of the Patents-in-Suit.

77. Upon information and belief, the amino acid sequence for the heavy chain variable region of galcanezumab corresponds to SEQ ID NO:63 of the Patents-in-Suit.

78. Upon information and belief, the light chain for galcanezumab is SEQ ID NO:29 in the ’838 patent and the heavy chain for galcanezumab is SEQ ID NO:34 in the ’838 patent. SEQ ID NOs:29 and 34 in the ’992 patent correspond to SEQ ID NOs:98 and 99, respectively, of the Patents-in-Suit.

79. Upon information and belief, the amino acid sequence for the light chain of galcanezumab corresponds to SEQ ID NO:98 of the Patents-in-Suit.

80. Upon information and belief, the amino acid sequence for the heavy chain of galcanezumab corresponds to SEQ ID NO:99 of the Patents-in-Suit.

81. Eli Lilly markets EMGALITY with labeling and product information in compliance with FDA requirements.

82. 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.*

83. The label (also known as the package insert) for EMGALITY includes instructions for how to use EMGALITY 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.

84. Eli Lilly instructs physicians how to use EMGALITY for the prevention of both episodic and chronic migraine, including how to administer an effective dose consistent with the FDA approved instructions.

85. Eli Lilly sells and markets EMGALITY pursuant to its FDA-approved label to be administered to patients for preventive treatment of chronic or episodic migraine at a loading dose of 240 mg, followed by monthly injections of 120 mg. Ex. 27 (12/2019 EMGALITY label).

86. Eli Lilly sells and markets EMGALITY pursuant to its FDA-approved label to be administered to patients for preventive treatment of chronic or episodic migraine in a 120 mg/mL liquid solution. *Id.*

87. Eli Lilly sells and markets EMGALITY pursuant to its FDA-approved label to be administered to patients for preventive treatment of chronic or episodic migraine by administering galcanezumab (the monoclonal antibody active ingredient of EMGALITY) in a liquid formulation "in a 1 mL single-dose prefilled pen to deliver 120 mg of galcanezumab-gnlm or a 1 mL single-dose prefilled syringe to deliver 100 mg or 120 mg of galcanezumab-gnlm. Each mL of solution contains 100 mg or 120 mg of galcanezumab-gnlm." *Id.*

88. Upon information and belief, Eli Lilly sells and markets EMGALITY pursuant to its FDA-approved label to be administered to patients for preventive treatment of chronic or episodic migraine by administering galcanezumab (the monoclonal antibody active ingredient of EMGALITY) in a liquid formulation at a volume of about 1 mL.

89. Eli Lilly sells and markets EMGALITY pursuant to its FDA-approved label to be administered to patients for preventive treatment of chronic or episodic migraine by administering galcanezumab (the monoclonal antibody active ingredient of EMGALITY) in a liquid formulation at "240 mg (two consecutive subcutaneous injections of 120 mg each)." *Id.*

90. Upon information and belief, Eli Lilly sells and markets EMGALITY pursuant to its FDA-approved label to be administered to patients for preventive treatment of chronic or episodic migraine by administering galcanezumab (the monoclonal antibody active ingredient of EMGALITY) in an initial loading dose in which each of the consecutive subcutaneous injections of 120 mg each is administered in a liquid formulation volume of about 1 mL, for a total volume of about 2 mL.

91. Eli Lilly sells and markets EMGALITY pursuant to its FDA-approved label to be administered to patients for preventive treatment of chronic or episodic migraine by administering a subcutaneous injection of galcanezumab (the monoclonal antibody active ingredient of EMGALITY) via a pre-filled syringe or a pre-filled pen (also known as an auto-injector) comprising a dose of the monoclonal antibody. *Id.*

B. Direct Infringement of the Patented Method

92. Upon information and belief, EMGALITY is prescribed in the U.S. by doctors in an effective dose in accordance with the FDA-approved EMGALITY label as a preventive treatment for patients who have been previously diagnosed with chronic or episodic migraine, with or without aura.

93. Upon information and belief, Eli Lilly knows that EMGALITY is prescribed in the U.S. by doctors in an effective dose in accordance with the FDA-approved EMGALITY label as a preventive treatment for patients who have been previously diagnosed with chronic or episodic migraine, with or without aura.

94. Insurance companies require that migraine patients first have failed at least two prior preventive migraine treatments and/or at least two classes of prior preventive migraine treatments before providing reimbursement for EMGALITY, and doctors prescribe EMGALITY in accordance with these policies. *See*, *e.g.*, Ex. 28 (Centene Corp Clinical Policy for EMGALITY) (approval criteria for EMGALITY include "[f]ailure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine)"); Ex. 29 (Wellmark Drug Policy for AJOVY and EMGALITY) (criteria for EMGALITY include "patient has had a trial of at least one of the listed medications in each of the following migraine prophylactic agent classes and experienced an inadequate response, has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the alternative migraine prophylactic agents . . . a.) Anticonvulsants (divalproex sodium, sodium valproate, topiramate) b.) Beta blockers (atenolol, metoprolol, nadolol, propranolol, timolol) c.) Antidepressants (amitriptyline, nortriptyline, venlafaxine)"); Ex. 30 (MassHealth Drug List at Table 14: Headache Therapy) (prior authorization requirements for EMGALITY include "inadequate response or adverse reaction to one of the following or contraindication to all of the following: atenolol, metoprolol, nadolol, propranolol, timolol; **and** one of the following: inadequate response or adverse reaction to one of the following: amitriptyline, Botox, topiramate, valproic acid, venlafaxine; **or** contraindication to all of the prophylactic alternatives above" (emphasis in original)); Ex. 2 (Blue Cross Blue Shield of Massachusetts Anti-Migraine Pharmacy Medical Policy) (coverage criteria for EMGALITY include "Patient has tried medications in at least two classes of the migraine prevention

treatments [topiramate, Beta blockers (e.g. propranolol, timolol), Valproic acid and its derivatives (e.g. divalproex sodium, and tricyclic antidepressants (e.g. amitriptyline)]" (brackets in original)).

95. Upon information and belief, Eli Lilly is aware of these reimbursement policies and aware that doctors in the U.S. practice the method of treatment claimed by the Patents-in-Suit by selecting migraine patients who previously failed at least two prior preventive treatments or classes of treatment and treating these patients with EMGALITY.

C. Eli Lilly's Active Inducement of Infringement of the Patented Method

96. Upon information and belief, Eli Lilly has acted and will continue to act with the specific intent to cause doctors to prescribe EMGALITY in the U.S. in the method of treating refractory migraine patients claimed by the Patents-in-Suit.

97. Eli Lilly advertises the results of post-hoc analyses of its EMGALITY clinical trials, focusing on a subgroup of refractory migraine patients, in promotional materials directed to U.S. healthcare providers. For example, on Eli Lilly touts on its EMGALITY webs under the heading "[d]iscover what Emgality® can do for patients with episodic migraine" that 53% of episodic migraine patients who "failed ≥2 preventives" "achieved ≥ 50% reduction in monthly MHDs" (migraine headache days) "over months 1 to 6." Ex. 31 ("Episodic Migraine Efficacy | Emgality® (galcanezumab-gnlm)," ELI LILLY, https://www.emgality.com/hcp/migraine/efficacy-episodic (last visited June 8, 2021)).

98. Similarly, Eli Lilly advertises to healthcare providers under the heading "[d]iscover what Emgality can do for patients with chronic migraine" that "mean change in monthly migraine headache days (MHDs) in patients with ≥2 prior preventive failures" was a decrease in 5.4. Ex. 32 ("Chronic Migraine Efficacy | Emgality® (galcanezumab-gnlm)," ELI LILLY, https://www.emgality.com/hcp/migraine/efficacy-episodic (last visited June 8, 2021)).

99. Eli Lilly has issued press releases and sponsored scientific papers promoting "positive results for Emgality (galcanezumab-gnlm) from the [a clinical trial] in patients who failed previous migraine treatments." Ex. 33 (Aug. 5, 2019 Press Release); Ex. 34 (Aug. 8, 2019 Press Release); Ex. 35 (May 26, 2020 Press Release); Ex. 36 (Apr. 24, 2018 Press Release); Ex. 37 (Dulanji Kuruppu et al., "Efficacy of galcanezumab in patients with migraine who did not benefit from commonly prescribed preventive treatments," BMC Neurology (2021) 21:175); Ex 38 (Wim Mulleners et al., "Safety and efficacy of galcanezumab in patients for whom previous migraine preventive medication from two to four categories had failed (CONQUER): a multicentre, randomised, double-blind, placebo-controlled, phase 3b trial," Lancet Neurol 2020; 19: 814–25); Ex. 39 (Todd Schwedt, "Early onset of effect following galcanezumab treatment in patients with previous preventive medication failures," J. of Headache and Pain (2021) 22:15); Ex. 40 (D. Ruff et al., Efficacy of galcanezumab in patients with episodic migraine and a history of preventive treatment failure: results from two global randomized clinical trials," European J. of Neurology 2020 Apr;27(4):609-618).

100. On information and belief, Eli Lilly knew and intended that these websites, press releases, and papers describing positive results for refractory migraine patients who were treated with EMGALITY would reach an audience including U.S. healthcare providers who would prescribe EMGALITY to refractory migraine patients.

101. Indeed, Eli Lilly has specifically targeted healthcare providers to induce them to prescribe EMGALITY to refractory migraine patients by promoting EMGALITY for this use.

102. For example, Eli Lilly's healthcare provider EMGALITY website provides two "hypothetical patient profiles," each of which states that the hypothetical EMGALITY patient "has tried therapeutic doses of 2 standard-of-care generic preventives." Ex. 41 ("Episodic

Migraine Efficacy | Emgality® (galcanezumab-gnlm)," ELI LILLY, https://www.emgality.com/hcp/migraine/efficacy-episodic (last visited June 8, 2021)); Ex. 42 ("Chronic Migraine Efficacy | Emgality® (galcanezumab-gnlm)," ELI LILLY, https://www.emgality.com/hcp/migraine/efficacy-chronic (last visited June 8, 2021)).

103. On information and belief, Eli Lilly intends for U.S. doctors to understand from these hypothetical EMGALITY patient profiles that EMGALITY should be prescribed as a preventive treatment for refractory migraine patients who have failed multiple prior preventive treatments.

104. Eli Lilly's healthcare provider EMGALITY website also provides a discussion of "treatment guidelines" and states that "Migraine preventives can only be prescribed by a licensed medical providera [sic] . . . . Patients must meet the appropriate criteria for one of the conditions listed below." The listed criteria for episodic migraine (described as "Migraine with or without aura (4-7 monthly headache days)") and chronic migraine ("Migraine with or without aura (8-14 monthly headache days)") both include "[i]nability to tolerate at least 2 prior preventive treatments due to side effects OR inadequate response to a 6-week trial of at least 2 prior preventive treatments." Ex. 43 ("Migraine for Healthcare Professionals I Emgality® (galcanezumab-gnlm)," ELI LILLY, https://www.emgality.com/hcp/migraine (last visited June 8, 2021)).

105. In addition, Eli Lilly provides on its EMGALITY healthcare provider website templates for doctors to use in submitting insurance coverage appeal letters and accompanying letters of medical necessity for the reimbursement of patient EMGALITY prescriptions. Ex. 44 (EMGALITY Preparing an Appeal Letter template, *available at* https://www.emgality.com/assets/pdf/sample_appeal_letter.pdf); Ex. 45 (EMGALITY

Composing a Letter of Medical Necessity template, *available at* https://www.emgality.com/assets/pdf/letter_of_medical_necessity.pdf). Both of these templates include sections for healthcare providers to fill in the patient's "past treatments used for the prevention of migraine, including any antidepressant, antiepileptic/anticonvulsant, beta blocker, calcium channel blocker, ACE inhibitor, or neurotoxin" along with "reasons for discontinuing." *Id.*

106. Eli Lilly's EMGALITY appeal letter template also includes the following instructions for healthcare providers in order to address step therapy requirements (i.e., those requiring prior treatment failures before reimbursing EMGALITY): "Please provide statement(s) indicating why these step therapy requirements are inappropriate for this patient. Include examples of previous treatments and failures with other therapies due to lack of response or intolerance to the drug." Ex. 44 (EMGALITY Preparing an Appeal Letter template, *available at* https://www.emgality.com/assets/pdf/sample_appeal_letter.pdf).

107. On information and belief, Eli Lilly intends for U.S. doctors to use the EMGALITY template appeal letter and letter of medical necessity to facilitate the prescription of EMGALITY to patients who have failed two or more prior preventive migraine treatments or classes of treatment as claimed by the Patents-in-Suit.

108. Eli Lilly also maintains a website entitled "Is EMGALITY® (galcanezumab-gnlm) effective in treatment-resistant migraine?" (the "EMGALITY treatment-resistant migraine webpage") as part of the www.lillymedical.com/en-us web domain. Ex. 46 (Is EMGALITY® (galcanezumab-gnlm) effective in treatment-resistant migraine?" LILLY MEDICAL, https://www.lillymedical.com/en-us/answers/is-emgality-galcanezumab-gnlm-effective-in-treatment-resistant-migraine-109331 (last visited June 8, 2021)).

109. Eli Lilly's www.lillymedical.com web domain was "created for US Healthcare Professionals." Ex. 47 (Healthcare Provider Pop-Up for (Is EMGALITY® (galcanezumab-gnlm) effective in treatment-resistant migraine?" LILLY MEDICAL, https://www.lillymedical.com/en-us/answers/is-emgality-galcanezumab-gnlm-effective-in-treatment-resistant-migraine-109331 (last visited June 8, 2021)).

110. The EMGALITY treatment-resistant migraine webpage describes the CONQUER trial, which "assessed the efficacy and safety of galcanezumab in adult patients with episodic migraine or chronic migraine who had not benefited from 2 to 4 previous migraine preventive medication categories." Ex. 46 (EMGALITY treatment-resistant migraine webpage).

111. The EMGALITY treatment-resistant migraine webpage defines "treatment resistance" as "previous failure of 2 to 4 migraine preventive medication categories in the past 10 years due to inadequate efficacy (after ≥2 months at maximum tolerated dose), or safety or tolerability reasons." *Id.*

112. The "categories" of migraine preventive medication categories identified by the EMGALITY treatment-resistant migraine webpage are "propranolol or metoprolol, topiramate, valproate or divalproex, amitriptyline, flunarizine, candesartan, botulinum toxin A or B (if taken for chronic migraine), or medication locally approved for the prevention of migraine." *Id.*

113. The website provides a table identifying the characteristics of the CONQUER trial study population, which indicates that patients were enrolled who had previously been treated with topiramate, amitriptyline, propranolol or metoprolol, valproate or divalproex, botulinum toxin A or B, candesartan, and flunarizine." *Id.*

114. On information and belief, Eli Lilly created the EMGALITY treatment-resistant migraine website in order to suggest to U.S. healthcare providers that the answer is "yes" to the

question posed as the heading to the website: "Is EMGALITY® (galcanezumab-gnlm) effective in treatment-resistant migraine?"

115. In particular, the EMGALITY treatment-resistant migraine website promotes EMGALITY's active ingredient, galcanezumab, as having "significantly reduced the mean monthly migraine headache days across months 1 to 3 in the total population and in each subpopulation (episodic migraine and chronic migraine)," reporting mean reductions of 4.1, 2.9, and 6.0 in the general population and each subgroup. *Id.*

116. Furthermore, the EMGALITY treatment-resistant migraine website promotes galcanezumab as having met "[a]ll key secondary endpoints" and having been "superior to placebo across all populations in reducing" the "number of monthly days with acute headache medication use, and number of monthly migraine headache days with acute headache medication use." *Id.*

117. On information and belief, Eli Lilly's clinical, marketing, and promotional activities related to the use of EMGALITY in refractory migraine patients are intended to cause doctors to prescribe EMGALITY in the U.S. in the method of treating refractory migraine patients claimed by the Patents-in-Suit.

118. On information and belief, Eli Lilly will continue these clinical, marketing, and promotional activities after the filing of this Complaint.

COUNT I FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '160 PATENT

119. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-118.

120. Upon information and belief, Defendant manufactures, markets, sells, offers to sell, and/or imports EMGALITY.

121. Defendant's activities in support of its manufacture, importation, and launch of EMGALITY for commercial sale in the United States, including Defendant's marketing and promotion of EMGALITY, 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 '160 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.

122. On information and belief, Eli Lilly has actual knowledge of the issuance of the '160 patent.

123. Eli Lilly should know of the issuance of the '160 patent.

124. On information and belief, U.S. healthcare providers directly infringe the '160 patent by prescribing EMGALITY to refractory migraine patients using the claimed method. This use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '160 patent.

125. On information and belief, Eli Lilly knows or should know of this direct infringement of the '160 patent by healthcare providers.

126. On information and belief, Eli Lilly has marketed and promoted EMGALITY for use to treat refractory migraine patients with the specific intent to induce U.S. healthcare providers to treat refractory migraine patients with EMGALITY.

127. The '160 patent issued in the early hours of the morning on June 8, 2021.

128. On information and belief, despite being aware of the imminent issuance of the '160 patent, Eli Lilly chose to maintain the public accessibility of its prior marketing and

promotional websites, press releases, and other materials that encourage U.S. healthcare providers to directly infringe the ’160 patent by prescribing EMGALITY to refractory migraine patients.

129. On information and belief, Eli Lilly will continue marketing and promoting EMGALITY for this infringing use, inducing infringement of the ’160 patent.

COUNT II FOR INFRINGEMENT OF THE ’160 PATENT

130. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-129.

131. On information and belief, Eli Lilly has actual knowledge of the issuance of the ’160 patent.

132. Eli Lilly should know of the issuance of the ’160 patent.

133. On information and belief, U.S. healthcare providers directly infringe the ’160 patent by prescribing EMGALITY to refractory migraine patients using the claimed method. This use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the ’160 patent.

134. On information and belief, Eli Lilly knows or should know of this direct infringement of the ’160 patent by healthcare providers.

135. On information and belief, Eli Lilly has marketed and promoted EMGALITY for use to treat refractory migraine patients with the specific intent to induce U.S. healthcare providers to treat refractory migraine patients with EMGALITY.

136. On information and belief, Eli Lilly will continue marketing and promoting EMGALITY for this infringing use, inducing infringement of the ’160 patent.

137. Teva has suffered irreparable harm from Eli Lilly’s active inducement of infringement of the Patents-in-Suit, and Teva is entitled to monetary and equitable relief.

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

COUNT III FOR DECLARATORY JUDGMENT OF INFRINGEMENT AS TO THE '161 PATENT

139. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-138.

140. Upon information and belief, Defendant manufactures, markets, sells, offers to sell, and/or imports EMGALITY.

141. Defendant's activities in support of its manufacture, importation, and launch of EMGALITY for commercial sale in the United States, including Defendant's marketing and promotion of EMGALITY, 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 '161 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.

142. On information and belief, Eli Lilly has actual knowledge of the issuance of the '161 patent.

143. Eli Lilly should know of the issuance of the '161 patent.

144. On information and belief, U.S. healthcare providers directly infringe the '161 patent by prescribing EMGALITY to refractory migraine patients using the claimed method. This use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the '161 patent.

145. On information and belief, Eli Lilly knows or should know of this direct infringement of the ’161 patent by healthcare providers.

146. On information and belief, Eli Lilly has marketed and promoted EMGALITY for use to treat refractory migraine patients with the specific intent to induce U.S. healthcare providers to treat refractory migraine patients with EMGALITY.

147. The ’161 patent issued in the early hours of the morning on June 8, 2021.

148. On information and belief, despite being aware of the imminent issuance of the ’161 patent, Eli Lilly chose to maintain the public accessibility of its prior marketing and promotional websites, press releases, and other materials that encourage U.S. healthcare providers to directly infringe the ’161 patent by prescribing EMGALITY to refractory migraine patients.

149. On information and belief, Eli Lilly will continue marketing and promoting EMGALITY for this infringing use, inducing infringement of the ’161 patent.

COUNT IV FOR INFRINGEMENT OF THE ’161 PATENT

150. Teva realleges and incorporates by reference the allegations contained in ¶¶ 1-149.

151. On information and belief, Eli Lilly has actual knowledge of the issuance of the ’161 patent.

152. Eli Lilly should know of the issuance of the ’161 patent.

153. On information and belief, U.S. healthcare providers directly infringe the ’161 patent by prescribing EMGALITY to refractory migraine patients using the claimed method. This use satisfies each element and infringes, either literally or under the doctrine of equivalents, one or more claims of the ’161 patent.

154. On information and belief, Eli Lilly knows or should know of this direct infringement of the ’161 patent by healthcare providers.

155. On information and belief, Eli Lilly has marketed and promoted EMGALITY for use to treat refractory migraine patients with the specific intent to induce U.S. healthcare providers to treat refractory migraine patients with EMGALITY.

156. On information and belief, Eli Lilly will continue marketing and promoting EMGALITY for this infringing use, inducing infringement of the ’161 patent.

157. Teva has suffered irreparable harm from Eli Lilly’s active inducement of infringement of the Patents-in-Suit, and Teva is entitled to monetary and equitable relief.

158. 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, launch, and sale of EMGALITY infringes each of the Patents-in-Suit,

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

C. Any available injunctive relief to prevent the inducement of healthcare providers to infringe the each of the Patents-in-Suit pursuant to 35 U.S.C. § 283, 28 U.S.C. § 2202, and FED. R. CIV. P. 65;

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

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

F. Costs and expenses in this action; and

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

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

Dated: June 8, 2021

Respectfully Submitted,

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