Keith J. Miller
ROBINSON MILLER LLC
One Newark Center
19th Floor
Newark, NJ 07102
(973) 690-5400
kmiller@rwmlegal.com

William F. Lee
Lisa J. Pirozzolo
Emily R. Whelan
Anna E. Lumelsky
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State St.
Boston, MA 02109
(617) 526 6000

Christopher R. Noyes
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
New York, NY 10007
(212) 230-8800

Attorneys for Plaintiffs
GlaxoSmithKline Biologicals S.A. and GlaxoSmithKline, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GLAXOSMITHKLINE BIOLOGICALS S.A. AND GLAXOSMITHKLINE LLC, Plaintiffs, v. PFIZER, INC., Defendant.	Civil Action No. 15-cv-01283-NLH-AMD ***Document electronically filed***

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

Plaintiffs GlaxoSmithKline Biologicals S.A. ("GSK Biologicals") and GlaxoSmithKline LLC ("GSK LLC") (collectively, "GSK") by their attorneys, for their Second Amended Complaint, allege as follows:

1. GSK Biologicals is a corporation organized and existing under the laws of Belgium with its principal place of business at Rue De L'Institut 89, Rixensart 1330, Belgium. GSK Biologicals is the human vaccine research, development and commercialization arm of GlaxoSmithKline plc. GSK Biologicals is working to develop and improve vaccines to cover a range of global diseases, including HIV, influenza, malaria, and tuberculosis. GSK Biologicals makes and sells BEXSERO® ("Bexsero"), a vaccine approved by the U.S. Food and Drug Administration ("FDA") for active immunization to prevent invasive disease caused by *N. meningitidis* serogroup B in individuals 10 through 25 years of age.

2. GSK LLC is a limited liability corporation organized and existing under the laws of Delaware with its principal place of business at 5 Crescent Drive, Philadelphia, Pennsylvania. GSK LLC is a research-based pharmaceutical company. GSK Biologicals has designated GSK LLC as the exclusive distributor of products covered by the GSK Patents (defined in paragraph 4, below) in the United States, including Bexsero.

3. Defendant Pfizer, Inc. ("Pfizer") is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 235 East 42nd Street, New York, New York.

4. This is an action for infringement of U.S. Patent Nos. 7,576,176 ("the '176 patent"), 8,524,251 ("the '251 patent"), 8,394,390 ("the '390 patent"), 8,398,988 ("the '988 patent"), 8,840,907 ("the '907 patent"), 8,834,888 ("the '888 patent"), 8,980,286 ("the '286 patent"), 9,266,929 ("the '929 patent"), 9,249,198 ("the '198 patent"), 9,249,196 ("the '196

patent"), 9,067,987 ("the '987 patent") and 9,056,075 ("the '075 patent") (collectively, the "GSK Patents"). The action arises out of the manufacture, importation, offer for sale, and sale by Pfizer of a meningococcus B vaccine, bivalent rLP2086 ("Bivalent rLP2086"), infringing one or more claims of the GSK Patents.

5. Bivalent rLP2086 has been approved by the FDA under the trade name TRUMENBA® ("Trumenba"). Upon information and belief, Pfizer manufactures Trumenba either through or in conjunction with its wholly owned subsidiary, Pfizer Ireland Pharmaceuticals ("Pfizer Ireland"). *See* Exhibit 1 (Trumenba label stating that Trumenba is manufactured by Pfizer Ireland Pharmaceuticals); Exhibit 2 (Betsy Hammond, *University of Oregon meningitis vaccination will be largest in US since approval of new drug*, The Oregonian, Feb. 26, 2015, http://www.oregonlive.com/education/index.ssf/2015/02/university_of_oregon_meningiti.html, ("[Trumenba] is made in Ireland.")).

6. Upon information and belief, Pfizer sells Trumenba either through or in conjunction with its wholly owned subsidiary, Wyeth Pharmaceuticals, Inc. ("Wyeth"). Wyeth, acting on behalf of Pfizer, holds the approved Biologics License Application ("BLA") for Trumenba.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Pfizer is subject to personal jurisdiction in this District because, upon information and belief, Pfizer has purposely availed itself of the rights and benefits of the laws of New Jersey by engaging in persistent, systematic and continuous contacts with New Jersey. Among other things, Pfizer maintains operations in New Jersey, and is in the business of marketing

pharmaceutical products, which it distributes and sells throughout the United States, including in New Jersey.

9. Upon information and belief, Pfizer regularly and continuously transacts business within New Jersey, including availing itself of the privilege of conducting business in New Jersey. For example, Pfizer is registered with the New Jersey Department of the Treasury to conduct business in New Jersey. *See* Exhibit 3 (New Jersey Business Gateway Business Entity Information and Records Service, Report for Pfizer, Inc.). Pfizer has also appointed an in-state agent for service by process in New Jersey. *See id.* Pfizer also holds a Drug and Medical Device Certificate of Registration with the New Jersey Department of Health and Senior Services, which upon information and belief, allows Pfizer to manufacture pharmaceutical products in New Jersey, and to ship those products wholesale into or out of New Jersey. *See* Exhibit 4 (Drug and Medical Device Certificate of Registration for Pfizer, Inc.).

10. Upon information and belief, Pfizer offers Trumenba for sale in the United States, including in New Jersey. Exhibit 5 (Pfizer press release stating that "[o]rders for TRUMENBA may be placed by contacting Pfizer Customer Services"). Pfizer also maintains a website for Trumenba, http://www.trumenba.com, which promotes Trumenba in the United States, including in New Jersey. Upon information and belief, Trumenba is available for use in New Jersey and recognized by the New Jersey Department of Health as a vaccine approved to protect against *N. meningitidis* serogroup B.

11. Upon information and belief, Pfizer, either alone, or through or in conjunction with one of its subsidiaries, conducted development of Trumenba in New Jersey, including, for example, sponsoring a Phase III clinical trial for Trumenba in Hackensack, New Jersey.

12. In addition, Pfizer has previously availed itself of this forum for the purpose of litigating patent disputes, including by filing counterclaims of non-infringement and invalidity in this case. *See* Docket No. 35 at 20-25. Pfizer has previously filed patent infringement lawsuits in this District. *See, e.g., Pfizer, Inc. v. Sandoz, Inc.*, Case No. 3:12-cv-03880-PGS-LHG (D.N.J.); *Pfizer, Inc. v. Zydus Pharmaceuticals (USA), Inc.*, Case No. 3:12-cv-03893-PGS-LHG (D.N.J). Pfizer has also previously been sued in this District and admitted that it is subject to personal jurisdiction. *See, e.g., Biogen Idec Ma Inc. v. EMD Serono, Inc.*, Case No. 2:10-cv-02760-CCC-JBC (D.N.J.), Docket No. 57 at ¶ 21; *Armkel, LLC. v. Pfizer, Inc.*, Case No. 1:02-cv-04206-FLW-AMD (D.N.J.), Docket No. 7 ¶ 5. Pfizer has also successfully moved to transfer litigation to this District. *See, e.g., Simonian v. Pfizer, Inc.*, Case No. 2:11-cv-03265-ES-CLW (D.N.J.), Docket Nos. 51, 61; *San Francisco Tech., Inc. v. Pfizer, Inc.*, Case No. 2:11-cv-03865-JLL-MAH (D.N.J.), Docket Nos. 16, 29.

13. Upon information and belief, Pfizer has committed and continues to commit acts of patent infringement in New Jersey, and has harmed and continues to harm GSK by offering to sell and/or selling products infringing the GSK Patents in New Jersey.

14. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

A. PIONEERING INVENTIONS OF DR. RAPPUOLI AND COLLEAGUES

15. This dispute involves infringement by Pfizer of twelve U.S. patents assigned to GSK Biologicals. Among other things, the patents at issue describe and claim the pioneering inventions of Dr. Rino Rappuoli and his colleagues, relating to a *N. meningitidis* serogroup B ("MenB") vaccine.

16. Prior to the groundbreaking inventions of Dr. Rappuoli and his colleagues, there was a longstanding, unmet need for a vaccine that would provide broad-based protective immunity against MenB. *N. meningitidis* can cause serious, life-threatening meningitis and septicemia, especially in the young. Strains of this bacterium are divided into "serogroups," and the "B" serogroup is one of the leading causes of bacterial meningitis in the developed world, including in the United States. Capsular polysaccharides, which cloak the outside of certain bacteria, have often been used in vaccine development, and have been shown to provide protective immunity for other *N. meningitidis* serogroups. This approach proved difficult with MenB, however, likely because its capsular polysaccharide is similar to a carbohydrate component of certain human glycoproteins.

17. In the 1990's, Dr. Rappuoli began work on a new approach for developing vaccines. This approach, which he coined "reverse vaccinology," has been described as revolutionary. It permits characterization of antigens independent of their abundance and immunogenicity during infection, without the need to grow the pathogen itself.

18. Dr. Rappuoli and his colleagues designed and implemented a plan to use reverse vaccinology to identify vaccine candidates for MenB. Their work ultimately resulted in the development of Bexsero, the first vaccine shown to provide protective immunity against a broad range of MenB strains. Bexsero is approved in more than thirty countries, including Canada, Australia, the U.S., and numerous countries across the European Union. Since Bexsero's launch in 2013, over half a million doses have been distributed worldwide. In 2014, under an investigational new drug designation from the FDA, nearly 30,000 doses of Bexsero were given to students and staff at Princeton University and the University of California, Santa Barbara following MenB outbreaks on their campuses. Further, the U.S. Centers for Disease Control and

Prevention have recommended that certain incoming freshman at Princeton University receive Bexsero.

19. On or about April 7, 2014, the FDA granted Bexsero a Breakthrough Therapy designation, intended to expedite the development and review of new medicines that treat serious or life-threatening conditions. On or about July 24, 2014, a BLA for marketing approval for Bexsero in the U.S. was submitted to the FDA. On January 23, 2015, the FDA announced that it had approved Bexsero for marketing and sale to prevent invasive meningococcal disease caused by MenB in individuals 10 through 25 years of age.

B. ASSERTED PATENTS

20. The twelve U.S. patents assigned to GSK Biologicals and at issue in this case describe and claim inventions of Dr. Rappuoli and his colleagues.

21. The '176 patent, issued on August 18, 2009, is entitled *"Neisseria Meningitidis* Antigens and Compositions," and is solely assigned to GSK Biologicals. A true and correct copy of the '176 patent is attached as Exhibit 6.

22. The '251 patent, issued on September 3, 2013, is entitled *"Neisseria Meningitidis* Antigens and Compositions," and is solely assigned to GSK Biologicals. A true and correct copy of the '251 patent is attached as Exhibit 7.

23. The '390 patent, issued on March 12, 2013, is entitled "Neisserial Antigenic Peptides," and is solely assigned to GSK Biologicals. A true and correct copy of the '390 patent is attached as Exhibit 8.

24. The '988 patent, issued on March 19, 2013, is entitled "Adjuvanting Meningococcal Factor H Binding Protein," and is solely assigned to GSK Biologicals. A true and correct copy of the '988 patent is attached as Exhibit 9.

25. The '907 patent, issued on September 23, 2014, is entitled "Isolated Protein and Compositions Comprising the Protein," and is solely assigned to GSK Biologicals. A true and correct copy of the '907 patent is attached as Exhibit 10.

26. The '888 patent, issued on September 16, 2014, is entitled "Adjuvanting Meningococcal Factor H Binding Protein," and is solely assigned to GSK Biologicals. A true and correct copy of the '888 patent is attached as Exhibit 11.

27. The '286 patent, issued on March 17, 2015, is entitled "Multiple Variants of Meningococcal Protein NBM1870," and is solely assigned to GSK Biologicals. A true and correct copy of the '286 patent is attached as Exhibit 12.

28. The '929 patent, issued on February 23, 2016, is entitled "*Nesisseria Meningitidis* Antigens and Compositions," and is solely assigned to GSK Biologicals. A true and correct copy of the '929 patent is attached as Exhibit 13.

29. The '198 patent, issued on February 2, 2016, is entitled "*Neisseria Meningitidis* Antigens and Compositions," and is solely assigned to GSK Biologicals. A true and correct copy of the '198 patent is attached as Exhibit 14.

30. The '196 patent, issued on February 2, 2016, is entitled "*Neisseria Meningitidis* Antigens and Compositions," and is solely assigned to GSK Biologicals. A true and correct copy of the '196 patent is attached as Exhibit 15.

31. The '987 patent, issued on June 30, 2015, is entitled "Neisserial Antigenic Peptides," and is solely assigned to GSK Biologicals. A true and correct copy of the '987 patent is attached as Exhibit 16.

32. The '075 patent, issued on June 16, 2015, is entitled "Methods of Inducing an Immune Response with Compositions Comprising a *Neisseria Meningitidis* 741 Protein," and is

solely assigned to GSK Biologicals. A true and correct copy of the '075 patent is attached as Exhibit 17.

C. PFIZER'S INFRINGING VACCINE

33. Pfizer's Bivalent rLP2086 vaccine (sold as Trumenba) practices one or more of the inventions claimed in the '176, '251, '390, '988, '907, '888, '286, '929, '198, '196, '987 and '075 patents.

34. On or before June 14, 2014, Pfizer, through its wholly-owned subsidiary Wyeth, submitted a BLA for Bivalent rLP2086 to the FDA. On October 29, 2014, the FDA approved the BLA for Bivalent rLP2086. The FDA states that Bivalent rLP2086, known by its trade name Trumenba, is "licensed in the United States to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age." The approved label for the product, attached as Exhibit 18, states:

> Trumenba is a sterile suspension composed of two recombinant lipidated factor H binding protein (fHBP) variants from *N. meningitidis* serogroup B, one from fHBP subfamily A and one from subfamily B (A05 and B01, respectively). The proteins are individually produced in *E. coli*. Production strains are grown in defined fermentation growth media to a specific density. The recombinant proteins are extracted from the production strains and purified through a series of column chromatography steps. Polysorbate 80 (PS80) is added to the drug substances and is present in the final drug product.
>
> Each 0.5 mL dose contains 60 micrograms of each fHBP variant (total of 120 micrograms of protein), 0.018 mg of PS80 and 0.25 mg of Al^{3+} as $AlPO_4$ in 10 mM histidine buffered saline at pH 6.0.

Trumenba Label, Exhibit 18 at 6-7.

35. Trumenba is an immunogenic vaccine composition. Its FDA-approved label states that "Trumenba is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. Trumenba is approved for use in individuals 10 through 25

years of age. Approval of Trumenba is based on demonstration of immune response, as measured by serum bactericidal activity against four serogroup B strains representative of prevalent strains in the United States." Trumenba Label, Exhibit 18 at 2.

36. The FDA-approved label for Trumenba instructs health professionals to "[a]dminister Trumenba as a three dose series (0.5 mL each) according to a 0-, 2-, and 6-month schedule. . . . Inject each 0.5 mL dose intramuscularly, using a sterile needle attached to the supplied prefilled syringe. The preferred site for injection is the deltoid muscle of the upper arm." Trumenba Label, Exhibit 18 at 2.

37. Upon information and belief, Trumenba has been administered to individuals in the United States.

38. According to its FDA-approved label, Pfizer's Trumenba vaccine includes two *Neisseria* meningitidis serogroup B recombinant lipidated factor H binding proteins ("fHBP"s) from subfamily A and subfamily B. The proteins are individually produced in *E. coli*. Production strains are grown in defined fermentation growth media to a specific density. The recombinant proteins are extracted from the production strains and purified through a series of column chromatography steps. *See* Trumenba Label, Exhibit 18 at 6.

39. According to its FDA-approved label, Pfizer's Trumenba vaccine includes an aluminum salt adjuvant. *See* Trumenba Label, Exhibit 18 at 7.

40. Upon information and belief, Pfizer's Trumenba vaccine is formulated by and filled at Pfizer's wholly-owned subsidiary, Pfizer Ireland, in Dublin, Ireland. *See supra* ¶ 5; http://www.ispe.org/ireland/agm-galadinner/gampcop, Exhibit 19 (stating that Pfizer fills its meningitis B vaccine candidate at Pfizer Grange Castle location).

41. Upon information and belief, the formulated Trumenba vaccine is imported into the United States by Pfizer, either alone, or through or in conjunction with a subsidiary acting on Pfizer's behalf.

42. Upon information and belief, on November 18, 2014, Pfizer began offering Trumenba for sale to healthcare providers, retail pharmacies, hospitals, and college health centers in the U.S., including in New Jersey. This manufacture, use, offer for sale, sale, and/or importation of Trumenba infringes at least one claim of each of the GSK Patents.

D. PFIZER'S KNOWLEDGE OF THE PATENTS-IN-SUIT

43. Upon information and belief, Pfizer had pre-suit knowledge of at least the '176, '251, '390, '988, '907, and '888 patents.

44. The '176 patent was cited by the U.S. Patent & Trademark Office ("PTO") and two different patent prosecutors working on behalf of Pfizer during the prosecution of U.S. Patent Nos. 8,101,194 ("the '194 patent"); 8,563,006 ("the '006 patent"); 8,563,007 ("the '007 patent"); and 8,574,597 ("the '597 patent"), which are owned by subsidiaries of Pfizer. These citations occurred on January 6, 2011; April 9, 2012; July 1, 2013; and August 28, 2012, respectively.

45. The WIPO publication (WO 03/20756) of the '907 patent's priority PCT application was cited by Pfizer patent prosecutors during the prosecution of the '194, '006, '007, and '597 patents on May 9, 2005; April 9, 2012; July 1, 2013; and October 3, 2012, respectively.

46. The WIPO publication (WO 01/31019) of the '390 patent's priority PCT application was also cited by a Pfizer patent prosecutor during the prosecution of the '006, '007, and '597 patents. These citations occurred on September 27, 2012; July 1, 2013; and October 3, 2012, respectively.

47. The WIPO publication (WO 99/57280) of the ’251 patent’s priority PCT application was cited by a Pfizer patent prosecutor during the prosecution of the ’006, ’007, and ’597 patents on April 9, 2012; July 1, 2013; and January 7, 2009, respectively.

48. The ’988 patent, which is the parent of the ’888 patent, was also cited by a Pfizer patent prosecutor during the prosecution of the ’006 patent, on September 4, 2013, and the ’007 patent, on July 15, 2013.

49. The WIPO publication (WO 04/048404) of the ’286 patent’s priority PCT application was cited by the PTO and/or by Pfizer patent prosecutors during the prosecution of the ’006 patent on July 16, 2012; February 4, 2013; May 16, 2013; and June 19, 2013. It was also cited by Pfizer patent prosecutors during prosecution of the ’007 patent on July 1, 2013, and cited by the PTO and/or by Pfizer patent prosecutors during prosecution of the ’597 patent on June 8, 2012; September 7, 2012; January 7, 2013; June 5, 2013; August 29, 2013; and September 24, 2013.

50. Upon information and belief, at the time Pfizer cited these patents and patent publications, Pfizer knew or should have known it was developing a vaccine that infringed the GSK Patents.

51. Additionally, upon information and belief, because Bexsero and Trumenba are the only vaccines FDA-approved to treat MenB, Pfizer closely tracks the status of patents and patent applications relating to MenB and Bexsero, and either knew or should have known that its actions would constitute infringement of the GSK Patents.

COUNT I -- INFRINGEMENT OF THE ’176 PATENT UNDER 35 U.S.C. § 271(a)

52. GSK incorporates each of the preceding paragraphs 1-51 as if fully set forth herein.

53. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the ’176 patent.

54. Upon information and belief, Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. The foregoing actions by Pfizer constitute infringement of the ’176 patent.

55. Pfizer has committed and will commit these acts of infringement without license or authorization.

56. As a result of Pfizer’s infringement of the ’176 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy

57. Upon information and belief, Pfizer knew of the ’176 patent prior to the filing of this Complaint.

58. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Trumenba does and will constitute an unjustifiably high risk of infringement of the ’176 patent.

59. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Trumenba. Thus, infringement by Pfizer is willful.

COUNT II -- INFRINGEMENT OF THE ’251 PATENT UNDER 35 U.S.C. § 271(a)

60. GSK incorporates each of the preceding paragraphs 1-59 as if fully set forth herein.

61. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '251 patent.

62. Upon information and belief, Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. The foregoing actions by Pfizer constitute infringement of the '251 patent.

63. Pfizer has committed and will commit these acts of infringement without license or authorization.

64. As a result of Pfizer's infringement of the '251 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

65. Upon information and belief, Pfizer knew of the '251 patent prior to the filing of this Complaint.

66. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Trumenba does and will constitute an unjustifiably high risk of infringement of the '251 patent.

67. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Trumenba. Thus, infringement by Pfizer is willful.

COUNT III -- INFRINGEMENT OF THE '390 PATENT UNDER 35 U.S.C. § 271(a)

68. GSK incorporates each of the preceding paragraphs 1-67 as if fully set forth herein.

69. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '390 patent.

70. Upon information and belief, Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. The foregoing actions by Pfizer constitute infringement of the '390 patent.

71. Pfizer has committed and will commit these acts of infringement without license or authorization.

72. As a result of Pfizer's infringement of the '390 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

73. Upon information and belief, Pfizer knew of the '390 patent prior to the filing of this Complaint.

74. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Trumenba does and will constitute an unjustifiably high risk of infringement of the '390 patent.

75. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Trumenba. Thus, infringement by Pfizer is willful.

COUNT IV -- INFRINGEMENT OF THE '988 PATENT UNDER 35 U.S.C. § 271(a)

76. GSK incorporates each of the preceding paragraphs 1-75 as if fully set forth herein.

77. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '988 patent.

78. Upon information and belief, Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. The foregoing actions by Pfizer constitute infringement of the '988 patent.

79. Pfizer has committed and will commit these acts of infringement without license or authorization.

80. As a result of Pfizer's infringement of the '988 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

81. Upon information and belief, Pfizer knew of the '988 patent prior to the filing of this Complaint.

82. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Trumenba does and will constitute an unjustifiably high risk of infringement of the '988 patent.

83. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Trumenba. Thus, infringement by Pfizer is willful.

COUNT V -- INFRINGEMENT OF THE '907 PATENT UNDER 35 U.S.C. § 271(a)

84. GSK incorporates each of the preceding paragraphs 1-83 as if fully set forth herein.

85. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '907 patent.

86. Upon information and belief, Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. The foregoing actions by Pfizer constitute infringement of the '907 patent.

87. Pfizer has committed and will commit these acts of infringement without license or authorization.

88. As a result of Pfizer's infringement of the '907 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

89. Upon information and belief, Pfizer knew of the '907 patent prior to the filing of this Complaint.

90. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Trumenba does and will constitute an unjustifiably high risk of infringement of the '907 patent.

91. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Trumenba. Thus, infringement by Pfizer is willful.

COUNT VI -- INFRINGEMENT OF THE '888 PATENT UNDER 35 U.S.C. § 271(a)

92. GSK incorporates each of the preceding paragraphs 1-91 as if fully set forth herein.

93. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '888 patent.

94. Upon information and belief, Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. The foregoing actions by Pfizer constitute infringement of the '888 patent.

95. Pfizer has committed and will commit these acts of infringement without license or authorization.

96. As a result of Pfizer's infringement of the '888 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

97. Upon information and belief, Pfizer knew of the '888 patent prior to the filing of this Complaint.

98. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Trumenba does and will constitute an unjustifiably high risk of infringement of the '888 patent.

99. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Trumenba. Thus, infringement by Pfizer is willful.

COUNT VII -- INFRINGEMENT OF THE '286 PATENT UNDER 35 U.S.C. § 271(a)

100. GSK incorporates each of the preceding paragraphs 1-99 as if fully set forth herein.

101. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '286 patent.

102. Upon information and belief, Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. The foregoing actions by Pfizer constitute infringement of the '286 patent.

103. Pfizer has committed and will commit these acts of infringement without license or authorization.

104. As a result of Pfizer's infringement of the '286 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

105. Upon information and belief, Pfizer knew of the '286 patent prior to the filing of this Complaint.

106. Upon information and belief, Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing Trumenba does and will constitute an unjustifiably high risk of infringement of the '286 patent.

107. Upon information and belief, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Trumenba. Thus, infringement by Pfizer is willful.

COUNT VIII -- INFRINGEMENT OF THE '929 PATENT UNDER 35 U.S.C. § 271(g)

108. GSK incorporates each of the preceding paragraphs 1-107 as if fully set forth herein.

109. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '929 patent.

110. Upon information and belief, Pfizer has engaged in the commercial use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. Trumenba is made by a process patented in the United States and Trumenba is not materially changed by subsequent processes prior to Pfizer's importation of Trumenba into the United States or Pfizer's offer to sell, sale, or use of Trumenba within the United States; nor does Trumenba become a trivial and nonessential component of another product. The foregoing actions by Pfizer constitute infringement of the '929 patent.

111. Pfizer has committed and will commit these acts of infringement without license or authorization.

112. As a result of Pfizer's infringement of the '929 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

COUNT IX -- INFRINGEMENT OF THE '198 PATENT UNDER 35 U.S.C. § 271(g)

113. GSK incorporates each of the preceding paragraphs 1-112 as if fully set forth herein.

114. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '198 patent.

115. Upon information and belief, Pfizer has engaged in the commercial use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. Trumenba is made by a process patented in the United States and Trumenba is not materially changed by subsequent processes prior to Pfizer's importation of Trumenba into the

United States or Pfizer's offer to sell, sale, or use of Trumenba within the United States; nor does Trumenba become a trivial and nonessential component of another product. The foregoing actions by Pfizer constitute infringement of the '198 patent.

116. Pfizer has committed and will commit these acts of infringement without license or authorization.

117. As a result of Pfizer's infringement of the '198 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

COUNT X -- INFRINGEMENT OF THE '196 PATENT UNDER 35 U.S.C. § 271(a)

118. GSK incorporates each of the preceding paragraphs 1-117 as if fully set forth herein.

119. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '196 patent.

120. Upon information and belief, Pfizer has engaged in the commercial use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. The foregoing actions by Pfizer constitute infringement of the '196 patent.

121. Pfizer has committed and will commit these acts of infringement without license or authorization.

122. As a result of Pfizer's infringement of the '196 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

COUNT XI -- INFRINGEMENT OF THE '987 PATENT UNDER 35 U.S.C. § 271(a)

123. GSK incorporates each of the preceding paragraphs 1-122 as if fully set forth herein.

124. The commercial manufacture, use, offer for sale, sale, and/or importation of Trumenba does and will constitute an act of infringement of one or more claims of the '987 patent.

125. Upon information and belief, Pfizer has engaged in the commercial use, offer for sale, or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. The foregoing actions by Pfizer constitute infringement of the '987 patent.

126. Pfizer has committed and will commit these acts of infringement without license or authorization.

127. As a result of Pfizer's infringement of the '987 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

COUNT XII -- INFRINGEMENT OF THE '075 PATENT UNDER 35 U.S.C. § 271(b)

128. GSK incorporates each of the preceding paragraphs 1-127 as if fully set forth herein.

129. The administration of Trumenba to a subject (for example, vaccinating an individual) directly infringes one or more claims of the '075 patent.

130. Upon information and belief, Pfizer has engaged in the offer for sale or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. Pfizer markets and sells Trumenba to health care professionals with specific dosing and administration instructions provided in the Trumenba label. *See supra* ¶¶ 36-42; https://www.pfizerpro.com/product/trumenba/neisseria-meningitidis# (Pfizer website for health care professionals regarding the administration of Trumenba); http://labeling.pfizer.com/ShowLabeling.aspx?id=1796 (Pfizer website with instructions regarding the administration of Trumenba). Pfizer also advertises Trumenba directly to consumers. *See* http://www.trumenba.com/; http://www.trumenba.com/information-for-

adolescents; http://www.trumenba.com/information-for-parents. The foregoing actions by Pfizer induce infringement of the '075 patent.

131. Pfizer does and will actively induce infringement of one or more claims of the '075 patent by the offer for sale, sale, and/or importation of Trumenba. Pfizer specifically intends and instructs health professionals to administer Trumenba to individuals. Pfizer is aware of the '075 patent and knows that the administration of Trumenba to an individual constitutes infringement of the '075 patent under 35 U.S.C. § 271(b).

132. Pfizer has committed and will commit these acts of infringement without license or authorization.

133. As a result of Pfizer's infringement of the '075 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

COUNT XIII -- INFRINGEMENT OF THE '075 PATENT UNDER 35 U.S.C. § 271 (c)

134. GSK incorporates each of the preceding paragraphs 1-133 as if fully set forth herein.

135. The administration of Trumenba to a subject (for example, vaccinating an individual) directly infringes one or more claims of the '075 patent.

136. Upon information and belief, Pfizer has engaged in the offer for sale or sale of Trumenba in the United States, and/or the importation of Trumenba into the United States. Pfizer markets and sells Trumenba to health care professionals with specific dosing and administration instructions provided in the Trumenba label. *See supra* ¶¶ 36-42; https://www.pfizerpro.com/product/trumenba/neisseria-meningitidis# (Pfizer website for health care professionals regarding the administration of Trumenba); http://labeling.pfizer.com/ShowLabeling.aspx?id=1796 (Pfizer website with instructions

regarding the administration of Trumenba). Pfizer also advertises Trumenba directly to consumers. *See* http://www.trumenba.com/; http://www.trumenba.com/information-for-adolescents; http://www.trumenba.com/information-for-parents. The foregoing actions by Pfizer contribute to infringement of the '075 patent.

137. Pfizer does and will contribute to infringement of one or more claims of the '075 patent. Pfizer sells, offers to sell or imports Trumenba within the United States. Trumenba is especially made or especially adapted for use in an infringement of the '075 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Trumenba constitutes a material part of the invention claimed in the '075 patent. Pfizer is aware of the '075 patent and knows that the administration of Trumenba to an individual constitutes infringement of the '075 patent under 35 U.S.C. § 271(c).

138. Pfizer has committed and will commit these acts of infringement without license or authorization.

139. As a result of Pfizer's infringement of the '075 patent, GSK will suffer irreparable injury for which monetary damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, GSK requests the following relief:

(a) Judgment that the manufacture, use, offer for sale, sale, and/or importation of Trumenba infringes one or more claims of the '176, '251, '390, '988, '907, '888, '286, '929, '198, '196, '987 and '075 patents;

(b) Judgment awarding GSK damages resulting from such infringement, increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

(c) Injunctive relief enjoining Pfizer, and all persons or entities acting in concert with Pfizer, from making, using, selling, offering for sale, or importing Trumenba, or any other

product the making, using, selling, offering for sale, or importing of which infringes one or more claims of the '176, '251, '390, '988, '907, '888, '286, '929, '198, '196, '987 and '075 patents;

(d) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(e) An award of GSK's costs and expenses in this action; and

(f) Such further and other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs demand a jury trial as to all matters triable of right by a jury.

Respectfully submitted,

Dated: March 15, 2016

s/ Keith J. Miller
Keith J. Miller
ROBINSON MILLER LLC
One Newark Center
19th Floor
Newark, NJ 07102
(973) 690-5400
kmiller@rwmlegal.com

William F. Lee
Lisa J. Pirozzolo
Emily R. Whelan
Anna E. Lumelsky
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State St.
Boston, MA 02109
(617) 526 6000

Christopher R. Noyes
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
New York, NY 10007
(212) 230-8800

Attorneys for Plaintiffs
GlaxoSmithKline Biologicals S.A. and
GlaxoSmithKline, LLC