IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., Plaintiff, v. WYETH LLC, Defendant.	C.A. No. 21-00024 (RGA) **DEMAND FOR JURY TRIAL**
WYETH LLC, WYETH HOLDINGS LLC, PFIZER IRELAND PHARMACEUTICALS, and PF PRISM IMB B.V., Counterclaim Plaintiffs, v. MERCK SHARP & DOHME CORP., Counterclaim Defendant.	

FIRST AMENDED ANSWER, DEFENSES, AND COUNTERCLAIMS TO COMPLAINT FOR DECLARATORY JUDGMENT

Defendant and Counterclaimant Wyeth LLC ("Wyeth"), by and through its attorneys, hereby submits its first amended answer and defenses to Plaintiff Merck Sharp & Dohme Corp.'s ("Merck") Complaint for Declaratory Judgment of Invalidity and Non-Infringement filed on January 11, 2021 ("Complaint"). In addition, Wyeth, Wyeth Holdings LLC, Pfizer Ireland Pharmaceuticals, and PF Prism IMB B.V. hereby submit the amended counterclaims herein against Merck.

ANSWER TO COMPLAINT

Each of the Paragraphs below corresponds to the same-numbered Paragraphs (each a "Paragraph") in the Complaint. Wyeth denies all allegations in the Complaint, whether express or implied, except those admitted specifically below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that Merck may argue follow from the admitted facts. Moreover, to the extent that any of Merck's allegations are vague and/or ambiguous, Wyeth denies said allegations. To the extent that any of the headings in the Complaint constitute allegations, Wyeth specifically denies each and every one of them. Wyeth reserves the right to amend this Answer or to assert other defenses or counterclaims as this action proceeds. Wyeth denies that Merck is entitled to the relief requested or any other relief.

INTRODUCTION

1. On information and belief, Wyeth admits that Merck has obtained approval to market vaccines to prevent diseases. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 1, and therefore denies those allegations.

2. Wyeth admits that the U.S. Food and Drug Administration ("FDA") approved the pneumococcal polysaccharide unconjugated vaccines called PNEUMOVAX® and PNEUMOVAX®23. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 2, and therefore denies those allegations.

3. Wyeth admits that Merck purports to seek FDA approval of a pneumococcal conjugate vaccine known as V114. Wyeth admits that PNEUMOVAX®23 is a pneumococcal

polysaccharide vaccine ("PPSV") whereas V114 is purportedly a pneumococcal conjugate vaccine ("PCV"). Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 3, and therefore denies those allegations.

4. Wyeth admits that Prevnar® and Prevnar13® are the only pneumococcal conjugate vaccines approved for use in the U.S. by FDA to date. Wyeth admits that Prevnar® is a 7-valent PCV and that Prevnar13® is a 13-valent PCV. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 4, and therefore denies those allegations.

5. Wyeth admits that Merck purports to have submitted a Biologics License Application ("BLA") for V114 on November 17, 2020 that was accepted for FDA review on January 11, 2021. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 5, and therefore denies them.

6. Wyeth admits that patent disputes have been initiated by Merck concerning Wyeth's patents relating to pneumococcal polysaccharide protein conjugate compositions. Wyeth denies the remaining allegations in Paragraph 6.

7. Wyeth admits that Merck's lawsuit seeks declaratory judgments of non-infringement and invalidity of U.S. Patent Nos. 8,895,024 ("the '024 patent"), 8,808,708 ("the '708 patent"), and 9,399,060 ("the '060 patent") (collectively, "the Patents-in-suit"). Wyeth denies that Merck is entitled to such relief. Wyeth denies the remaining allegations in Paragraph 7.

NATURE OF THIS ACTION

8. Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth admits that Merck's Complaint purports to bring a civil

action arising under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* and the patent laws of the United States, 35 U.S.C. § 100 *et seq.*. Wyeth denies the remaining allegations of Paragraph 8.

9. Wyeth admits that Merck's Complaint requests a declaratory judgment that the '024 patent, the '708 patent, and the '060 patent are either invalid, not infringed, or both. Wyeth denies that Merck is entitled to any such relief. Wyeth admits that Merck purports to attach true and correct copies of the '024 patent, the '708 patent, and the '060 patent to the Complaint. Wyeth denies the remaining allegations of paragraph 9.

10. Paragraph 10 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth denies the allegations in Paragraph 10.

THE PARTIES

11. Wyeth is without information or knowledge sufficient to form a belief about the truth of the allegations in Paragraph 11, and therefore denies them.

12. Admitted.

JURISDICTION AND VENUE

13. Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth admits that this action purports to arise under the patent laws of the United States and the Declaratory Judgment Act. Wyeth denies the remaining allegations of paragraph 13.

14. Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth admits that it is a Delaware limited liability company. Wyeth does not contest personal jurisdiction for purposes of this action only. Wyeth denies the remaining allegations of Paragraph 14.

15. Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth admits that it is incorporated in Delaware. Wyeth does not contest that venue is proper in this District for purposes of this action only. Wyeth denies the remaining allegations in Paragraph 15.

FACTUAL BACKGROUND

I. PNEUMOCOCCAL VACCINE TECHNOLOGY

16. Wyeth admits that this case concerns pneumococcal conjugate vaccines; such vaccines have been administered to persons to protect against infectious diseases caused by *S. pneumoniae*; such vaccines include PCVs and PPSVs; and that PPSVs are also called "unconjugated" vaccines. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 16, and therefore denies them.

17. Admitted.

18. Wyeth is without information or knowledge sufficient to form a belief about the truth of the allegations in Paragraph 18, and therefore denies them.

19. Wyeth admits that FDA approved the PPSVs known as PNEUMOVAX® and PNEUMOVAX®23. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 19, and therefore denies them.

20. Wyeth admits that *S. pneumoniae* polysaccharides can be conjugated to a carrier protein and that compared to pneumococcal polysaccharide vaccines, pneumococcal conjugate vaccines are provided for improved protection in children younger than two years old. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 20, and therefore denies them.

21. Wyeth admits that CRM_{197} is a carrier protein that has been used in conjugate vaccines. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 21, and therefore denies them.

22. Wyeth admits that Prevnar® is a 7-valent PCV developed by Wyeth. Wyeth admits that Prevnar® was approved in the United States in 2000, and that it was the first PCV approved for sale in the United States. Wyeth admits that a 13-valent PCV called Prevnar13® was approved for sale in the United States in 2010 and is currently marketed in the United States. Wyeth admits that Prevnar® and Prevnar13® are called Prevenar and Prevenar13, respectively, in some parts of the world. Wyeth admits the GlaxoSmithKline markets a 10-valent PCV, Synflorix™, outside the United States. Wyeth denies the remaining allegations in Paragraph 22.

II. MERCK'S AND WYETH'S PNEUMOCOCCAL VACCINES

23. Wyeth is without information or knowledge sufficient to form a belief about the truth of the allegations in Paragraph 23, and therefore denies them.

24. Wyeth admits that Paragraph 24 provides a list of vaccines purportedly developed and sold by Merck. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph, 24 and therefore denies them.

25. Admitted.

26. Admitted.

27. Wyeth admits that, for the U.S. market, Prevnar13® is marketed by Pfizer Inc. ("Pfizer") and manufactured by Wyeth Pharmaceuticals Inc. Wyeth denies the remaining allegations in Paragraph 27.

28. Wyeth admits that Merck purports to have developed a 15-valent PCV known as "V114." Wyeth admits that V114 purportedly contains capsular polysaccharides individually

conjugated to CRM_{197}. Wyeth admits that no PCV on the market to date contains 22F or 33F serotype conjugates, however, Pfizer is currently developing a PCV that contains serotypes including 22F and 33F. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 28, and therefore denies them.

III. MERCK V114 ANTICIPATED FDA APPROVAL

29. Wyeth admits that the webpage recited in Paragraph 29 links to a document entitled, "V114 Program Overview For Media Background, November 2020." Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 29, and therefore denies them.

30. Wyeth is without information or knowledge sufficient to form a belief about the truth of the allegations in Paragraph 30, and therefore denies them.

31. Wyeth admits that Merck purports to have submitted a BLA for V114 on November 17, 2020, that was purportedly accepted for review on January 11, 2021, and purports that the target date for approval is July 18, 2021. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 31, and therefore denies them.

32. Wyeth is without information or knowledge sufficient to form a belief about the truth of the allegations in Paragraph 32, and therefore denies them.

33. Wyeth admits that Merck purports to have received Breakthrough Therapy designations from FDA for V114. Wyeth is without information or knowledge sufficient to form a belief about the truth of the allegations in Paragraph 33, and therefore denies them.

34. Wyeth is without information or knowledge sufficient to form a belief about the truth of the allegations in Paragraph 34, and therefore denies them.

35. Wyeth admits that Merck purports to have made substantial investments in developing and bringing its V114 vaccine to market and plans to continue investing in V114; Merck purports to have already hired and continues to hire new employees to bring V114 to market, including employees dedicated to working on the development and manufacture of V114; and Merck purports to have made and will continue to make significant investments in preparation for obtaining expected FDA approval in July 2021. Wyeth is without information or knowledge sufficient to form a belief about the truth of the remaining allegations in Paragraph 35, and therefore denies them.

IV. WYETH'S PATENTS

36. Admitted.

37. Admitted.

38. Admitted.

39. Admitted.

40. Paragraph 40 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth admits that Wyeth, Pfizer, and/or affiliates thereof own or are listed assignees of additional United States and foreign patents related to pneumococcal conjugate vaccines. Wyeth denies the remaining allegations in Paragraph 40.

V. WYETH'S ENFORCEMENT OF ITS PATENTS AND CURRENT WORLD-WIDE DISPUTES BETWEEN MERCK AND WYETH

41. Wyeth admits that Wyeth and Merck have been involved in patent infringement and invalidity proceedings around the world, which Merck has initiated, concerning, inter alia, Wyeth's patents relating to pneumococcal conjugate vaccines, and Merck's V114 vaccine candidate. Wyeth denies the remaining allegations in Paragraph 41.

42. Wyeth admits that Wyeth and Merck have been involved in proceedings in Australia, Canada, the European Patent Office, Japan, Korea, the Netherlands, the United Kingdom, and the United States, which Merck has initiated. Wyeth admits that these proceedings involve Wyeth's patents relating to pneumococcal conjugate vaccines. The remaining allegations state a legal conclusion that requires no response.

43. Wyeth admits that Wyeth's Statement of Cross-Claim includes the statement that "[Merck] ha[s] threatened to infringe" claims 1-8, 11-13, and 18 of Patent AU2006235013 ("013 patent"); claims 1-6 and 11-14 of Patent AU2013206844 ("844 patent"); and claims 1-8, 16-18, and 20-23 of Patent AU2012216628 ("628 patent"). *See* Wyeth's Statement of Cross-Claim ¶ 12, *Merck Sharp & Dohme Corp. & Anor v. Wyeth LLC* (NSD 1381 of 2017) (Nov. 14, 2017) (Austl.). Wyeth denies the remaining allegations in Paragraph 43.

44. Wyeth admits that Paragraph 44 contains an accurate quotation of Wyeth's Closing Submission on Infringement ¶ 45. Wyeth further admits that the Federal Court of Australia found that the "asserted 013 patent claims are valid and will be infringed by [Merck's] 15-valent vaccine," "the asserted 844 patent claims would have been infringed, but are invalid because they lack support within s 40(3) of the post-RTB *Patents Act*," and "the asserted container patent claims would have been infringed, but that they are invalid for want of inventive step." *See* Orders ¶ 958, *Merck Sharp & Dohme Corporation v. Wyeth LLC* (No 3) [2020] FCA 1477 (NSD 1381 of 2017) (Oct. 14, 2020) (Austl.). Wyeth denies the remaining allegations of Paragraph 44.

45. Wyeth admits that Paragraph 45 contains an accurate quotation from Wyeth's Particulars of Infringement, prior to Wyeth's June 10, 2020 amendment thereto. Wyeth admits that Paragraph 45 contains an accurate quotation from Wyeth's Opening Trial Skeleton

Argument submitted to the High Court of Justice of England and Wales. Wyeth admits that the High Court's conclusions are summarized in Paragraph 366 of its Judgment. *See* Judgment ¶ 366, *Merck Sharp & Dohme Ltd. v. Wyeth LLC*, Case No. HP-2019-000005 [2020] EWHC 2636 (Pat) (Oct. 15, 2020). Wyeth denies the remaining allegations in Paragraph 45.

46. Wyeth admits that Paragraph 46 provides a list of proceedings which Merck has initiated around the world relating to Wyeth's patents relating to pneumococcal conjugate vaccines. Wyeth denies the remaining allegations in Paragraph 46.

47. Paragraph 47 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth admits that there are legal proceedings between Wyeth and Merck involving Wyeth's patents relating to pneumococcal conjugate vaccines. Wyeth denies the remaining allegations in Paragraph 47.

COUNT ONE: DECLARATORY JUDGMENT OF INVALIDITY OF THE '024 PATENT

48. Wyeth incorporates the preceding paragraphs by reference.

49. Admitted.

50. Denied.

51. Denied.

52. Wyeth admits that it contends the claims of the '024 patent cover Merck's V114 vaccine. Wyeth denies the remaining allegations in Paragraph 52.

53. Paragraph 53 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth denies that the claims of the '024 patent are invalid.

54. Paragraph 54 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth denies that the claims of the '024 patent are invalid.

55. Denied.

COUNT TWO: DECLARATORY JUDGMENT OF INVALIDITY OF THE '708 PATENT

56. Wyeth incorporates the preceding paragraphs by reference.

57. Admitted.

58. Denied.

59. Denied.

60. Paragraph 60 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth denies that the claims of the '708 patent are invalid. Wyeth further denies that Wyeth or its affiliates have asserted or will assert infringement of the '708 patent by Merck or its affiliates based on Merck's submission of a Biologics License Application ("BLA") for FDA approval of V114 on November 17, 2020, or importing, making, using, selling, or offering for sale products that are the subject of such BLA. As a result, Wyeth denies the allegations in Paragraph 60.

61. Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth denies that the claims of the '708 patent are invalid. Wyeth further denies that Wyeth or its affiliates have asserted or will assert infringement of the '708 patent by Merck or its affiliates based on Merck's submission of a BLA for FDA approval of V114 on November 17, 2020, or importing, making, using, selling, or offering for sale products that are the subject of such BLA. As a result, Wyeth denies the allegations in Paragraph 61.

62. Denied.

COUNT THREE: DECLARATORY JUDGMENT OF INVALIDITY OF THE '060 PATENT

63. Wyeth incorporates the preceding paragraphs by reference.

64. Admitted.

65. Denied.

66. Denied.

67. Wyeth admits that it contends the claims of the ’060 patent cover Merck’s V114 vaccine. Wyeth denies the remaining allegations in Paragraph 67.

68. Paragraph 68 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth denies that the claims of the ’060 patent are invalid.

69. Paragraph 69 contains legal conclusions to which no response is required. To the extent a response is required, Wyeth denies that the claims of the ’060 patent are invalid.

70. Denied.

COUNT FOUR: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’024 PATENT

71. Wyeth incorporates the preceding paragraphs by reference.

72. Admitted.

73. Wyeth admits that the ’024 patent contains claims directed to, inter alia, immunogenic compositions comprising polysaccharide-protein conjugates. Wyeth denies the remaining allegations in Paragraph 73.

74. Wyeth admits that Merck purports to contend that it does not and will not at or after commercialization of V114 infringe, directly or indirectly, any valid and enforceable claim of the ’024 patent.

75. Wyeth admits that Merck purports to contend that no valid claim of the ’024 patent encompasses any PCV of more than 13-valent. Wyeth denies the remaining allegations in Paragraph 75.

76. Paragraph 76 contains a legal conclusion to which no response is required. To the extent a response is required, Wyeth denies that the claims of the ’024 patent are not valid and denies that Merck does not and will not infringe the ’024 patent.

77. Paragraph 77 contains a legal conclusion to which no response is required. To the extent a response is required, Wyeth denies that the claims of the '024 patent are not valid and denies that Merck does not and will not infringe the '024 patent.

78. Denied.

COUNT FIVE: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '708 PATENT

79. Wyeth incorporates the preceding paragraphs by reference.

80. Wyeth admits that it is the owner of the '708 patent. Wyeth denies that Wyeth or its affiliates have asserted or will assert infringement of the '708 patent by Merck or its affiliates based on Merck's submission of a BLA for FDA approval of V114 on November 17, 2020, or the importing, making, using, selling, or offering for sale of products that are the subject of such BLA. As a result, Wyeth avers that the Court lacks subject matter jurisdiction over Count Five of Merck's Complaint.

81. Wyeth admits that the '708 patent contains claims directed to, inter alia, immunogenic compositions comprising polysaccharide-protein conjugates. Wyeth denies the remaining allegations of Paragraph 81.

82. Wyeth admits that Merck purports to contend that it does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '708 patent at or after commercialization of V114. Wyeth denies that Wyeth or its affiliates have asserted or will assert infringement of the '708 patent by Merck or its affiliates based on Merck's submission of a BLA for FDA approval of V114 on November 17, 2020, or the importing, making, using, selling, or offering for sale of products that are the subject of such BLA. As a result, Wyeth avers that the Court lacks subject matter jurisdiction over Count Five of Merck's Complaint.

83. Paragraph 83 contains a legal conclusion to which no response is required. To the extent a response is required, Wyeth admits that Merck purports to contend that no valid claim of the '708 patent encompasses any PCV of more than 13-valent and that Merck's V114 does not and will not infringe any valid and enforceable claim of the '708 patent. Wyeth denies that Wyeth or its affiliates have asserted or will assert infringement of the '708 patent by Merck or its affiliates based on Merck's submission of a BLA for FDA approval of V114 on November 17, 2020, or the importing, making, using, selling, or offering for sale of products that are the subject of such BLA. As a result, Wyeth avers that the Court lacks subject matter jurisdiction over Count Five of Merck's Complaint.

84. Paragraph 84 contains a legal conclusion to which no response is required. To the extent a response is required, Wyeth denies that Wyeth or its affiliates have asserted or will assert infringement of the '708 patent by Merck or its affiliates based on Merck's submission of a BLA for FDA approval of V114 on November 17, 2020, or the importing, making, using, selling, or offering for sale of products that are the subject of such BLA. As a result, Wyeth denies the allegations in Paragraph 84.

85. Paragraph 85 contains a legal conclusion to which no response is required. To the extent a response is required, Wyeth denies that Wyeth or its affiliates have asserted or will assert infringement of the '708 patent by Merck or its affiliates based on Merck's submission of a BLA for FDA approval of V114 on November 17, 2020, or the importing, making, using, selling, or offering for sale of products that are the subject of such BLA. As a result, Wyeth denies the allegations in Paragraph 85.

86. Denied.

COUNT SIX: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '060 PATENT

87. Wyeth incorporates the preceding paragraphs by reference.

88. Admitted.

89. Wyeth admits that the '060 patent contains claims directed to, inter alia, immunogenic compositions comprising polysaccharide-protein conjugates. Wyeth denies the remaining allegations of Paragraph 89.

90. Wyeth admits that Merck purports to contend that it does not infringe and will not at or after commercialization of V114 infringe, directly or indirectly, any valid and enforceable claim of the '060 patent.

91. Wyeth admits that Merck purports to contend that no valid claim of the '060 patent encompasses any PCV of more than 13-valent. Wyeth denies the remaining allegations in Paragraph 91.

92. Paragraph 92 contains a legal conclusion to which no response is required. To the extent a response is required, Wyeth denies that the claims of the '060 are not valid and denies that Merck does not and will not infringe the '060 patent.

93. Paragraph 93 contains a legal conclusion to which no response is required. To the extent a response is required, Wyeth denies that the claims of the '060 patent are not valid and denies that Merck does not and will not infringe the '060 patent.

94. Denied.

PRAYER FOR RELIEF

Wyeth denies that Merck is entitled to any relief sought in the Complaint or any other remedy or relief.

DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or truth of any allegation in the Complaint, Wyeth relies upon the following defenses to each claim asserted against it:

First Defense

All claims of the '024, '060, and '708 patents are valid and enforceable under 35 U.S.C. § 1 *et seq*., and Merck will not be able to demonstrate by clear and convincing evidence that they are otherwise.

Second Defense

Merck's V114 directly or indirectly infringes at least claim 1 of the '024 and '060 patents.

Third Defense

The Complaint fails to state a claim upon which relief may be granted.

Fourth Defense

Merck's claims and/or remedies are barred in whole or in part under principles of equity, including laches, estoppel, waiver, and/or unclean hands.

Fifth Defense

There is no justiciable controversy between the parties concerning Counts Two and Five of Merck's Complaint.

Sixth Defense

This Court lacks subject matter jurisdiction over Counts Two and Five of Merck's Complaint.

Reservation of Defenses

Wyeth's investigation of its defenses is continuing, and Wyeth expressly reserves the right to allege and assert any additional defenses. Wyeth has not knowingly or intentionally waived any applicable affirmative or other defenses and reserves the right to assert and rely upon such other affirmative and other defenses as may become available or apparent during discovery proceedings. Wyeth further reserves the right to amend this Answer and/or affirmative defenses accordingly.

AMENDED COUNTERCLAIMS

Counterclaim Plaintiffs Wyeth LLC, Wyeth Holdings LLC, Pfizer Ireland Pharmaceuticals, and PF Prism IMB B.V. ("Counterclaim Plaintiffs" or "Wyeth") hereby assert counterclaims against Plaintiff/Counterclaim Defendant Merck Sharp & Dohme Corp. ("Merck") as follows.

NATURE OF THE ACTION

1. This is an action for patent infringement and for a declaratory judgment of patent infringement against Merck for infringement of United States Patent No. 8,895,024 ("the '024 patent"); United States Patent No. 9,399,060 ("the '060 patent"); United States Patent No. 8,562,999 ("the '999 patent"); and United States Patent No. 9,675,681 ("the '681 patent"), arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

2. This action arises out of Merck's development of a 15-valent pneumococcal polysaccharide protein conjugate vaccine ("V114"), Merck's submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import V114 in the United States, the FDA's approval of Merck's BLA for V114, also known as Vaxneuvance, in July 2021 (*see* Merck Announces U.S. FDA Approval of VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) for the Prevention of Invasive Pneumococcal Disease in Adults 18 Years and Older Caused by 15 Serotypes, MERCK, https://www.merck.com/news/merck-announces-u-s-fda-approval-of-vaxneuvance-pneumococcal-15-valent-conjugate-vaccine-for-the-prevention-of-invasive-pneumococcal-disease-in-adults-18-years-and-older-caused-by-15-serot/ (last visited July 26, 2021)), and Merck's current and/or imminent manufacture, use, sale, offer to sell within

the United States, and/or importation into the United States, of V114 prior to the expiration of the '024, '060, '999, and '681 patents.

PARTIES

3. Wyeth LLC is a limited liability company organized and existing under the laws of the State of Delaware and having its principal place of business at 235 East 42nd Street, New York, New York 10017. Wyeth LLC is a wholly-owned subsidiary of Pfizer Inc. ("Pfizer").

4. Wyeth Holdings LLC is a limited liability company organized and existing under the laws of Maine and having its principal place of business at 235 East 42nd Street, New York, New York 10017.

5. Pfizer Ireland Pharmaceuticals ("Pfizer Ireland") is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland.

6. PF PRISM IMB B.V. is a private limited liability company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands.

7. On information and belief, Counterclaim Defendant Merck is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Merck is a wholly-owned subsidiary of Merck & Co., Inc., a New Jersey corporation that has its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

JURISDICTION AND VENUE

8. These Counterclaims are for patent infringement, which arise under the patent laws of the United States, Title 35, United States Code, and for declaratory judgment of patent infringement under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

9. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), and the Declaratory Judgment Act §§ 2201, 2202.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391, 1400(b).

11. Merck is registered to do business in the State of Delaware (File No. 4085682), is in good standing, and filed an annual report in 2019.

12. The Corporation Trust Company, located at 1209 Orange St., Corporation Trust Center, Wilmington, DE 19801, serves as Merck's Registered Agent in the State of Delaware.

13. This Court has personal jurisdiction over Merck by virtue of its presence in Delaware, having conducted business in Delaware, and having availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being haled into court in this judicial district.

14. Merck has filed this action for Declaratory Judgment and has thus submitted to this Court's personal jurisdiction.

15. On information and belief, Merck will, among other things, market, sell, and distribute V114 in the State of Delaware, and V114 will be prescribed by physicians practicing in the State of Delaware, become available at pharmacies located within the State of Delaware, and/or be used by patients in, and/or residents of, the State of Delaware.

16. Merck has previously availed itself of this Court and recently asserted claims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Ajanta*

Pharma Limited et al, No. 1:20-cv-00815-RGA (D. Del. June 17, 2020); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al,* No. 1:20-cv-00749-RGA (D. Del. June 3, 2020).

17. Similarly, Merck has previously availed itself of this Court by consenting to this Court's jurisdiction in other civil actions initiated in this jurisdiction. *See, e.g.*, S*anofi-Aventis US LLC et al v. Merck Sharp & Dohme Corp*., No. 1:16-cv-00812-RGA (D. Del. Sept. 16, 2016) (D.I. 8, D.I. 65).

PATENTS-IN-SUIT

18. On November 25, 2014, the USPTO issued the '024 patent, entitled "Multivalent Pneumococcal Polysaccharide-Protein Conjugate Composition." The '024 patent is duly and legally assigned to Wyeth LLC. A copy of the '024 patent is attached hereto as Exhibit A.

19. On July 26, 2016, the USPTO issued the '060 patent, entitled "Multivalent Pneumococcal Polysaccharide-Protein Conjugate Composition." The '060 patent is duly and legally assigned to Wyeth LLC. A copy of the '060 patent is attached hereto as Exhibit B.

20. On October 22, 2013, the USPTO issued the '999 patent, entitled "Formulations Which Stabilize and Inhibit Precipitation of Immunogenic Compositions." The '999 patent is duly and legally assigned to Wyeth LLC. A copy of the '999 patent is attached hereto as Exhibit C.

21. On June 13, 2017, the USPTO issued the '681 patent, entitled "Shortened Purification Process for the Production of Capsular *Streptococcus Pneumoniae* Polysaccharides." The '681 patent is duly and legally assigned to Wyeth LLC. A copy of the '681 patent is attached hereto as Exhibit D.

22. The '024, '060, '999, and '681 patents (collectively the "Patents-in-Suit") have been owned by Wyeth LLC at all times, are fully maintained, and are valid and enforceable.

BACKGROUND

I. PNEUMOCOCCAL VACCINES

23. Wyeth LLC is the global leader in the research and development of pneumococcal multivalent conjugate vaccines. In 2000, Wyeth LLC received approval in the United States for the first pneumococcal conjugate vaccine ("PCV"). This vaccine contained seven serotypes and was marketed as Prevnar®. Prevnar® impacted the trajectory of treatment against disease caused by *Streptococcus pneumoniae*, "reduc[ing] invasive disease caused by vaccine serotypes by 97%." *See* Vaccines and Preventable Diseases, CDC, https://www.cdc.gov/vaccines/vpd/pneumo/hcp/about-vaccine.html (last visited Jan. 25, 2021). Then in 2010, FDA approved a second breakthrough pneumococcal conjugate vaccine containing thirteen serotypes, Prevnar13®.

24. Prevnar13® is a market-leading vaccine in the pneumococcal conjugate vaccine market.

25. Pfizer is currently developing a PCV vaccine that extends the coverage of Prevnar13® to target 20 pneumococcal serotypes ("PCV20").

26. Pfizer submitted a Biologics License Application ("BLA") to FDA seeking approval for PCV20 in October 2020. FDA accepted the BLA and granted priority review in December 2020. Pfizer received FDA approval for PCV20 on June 8, 2021. *See* U.S. FDA Approves Prevnar20™, Pfizer's Pneumococcal 20-Valent Conjugate Vaccine for Adults 18 Years of Age and Older, PFIZER, https://www.pfizer.com/news/press-release/press-release-detail/us-fda-approves-prevnar-20tm-pfizers-pneumococcal-20-valent (last visited July 26, 2021).

27. FDA previously awarded PCV20 Fast Track Designation in September 2017, and on September 20, 2018, Pfizer announced FDA granted Breakthrough Therapy designation for PCV20 for use in adults aged 18 years or older. *See* U.S. FDA Accepts for Priority Review the Biologics License Application for Pfizer's Investigational 20-Valent Pneumococcal Conjugate Vaccine for Adults 18 Years of Age and Older, PFIZER, https://www.pfizer.com/news/press-release/press-release-detail/us-fda-accepts-priority-review-biologics-license (last visited Feb. 20, 2021).

28. PCV20 expands protection to seven new serotypes not included in Prevnar13®, which have been identified as "global causes of invasive pneumococcal disease (IPD) and are associated with high case-fatality rates, antibiotic resistance, and/or meningitis." *See* Pfizer Announces Positive Results On 20-Valent Pneumococcal Conjugate Vaccine, NASDAQ, https://www.nasdaq.com/articles/pfizer-announces-positive-results-on-20-valent-pneumococcal-conjugate-vaccine-2020-05-14 (last visited Feb. 20, 2021). The seven new serotypes include serotypes 22F and 33F. The 20 serotypes included in PCV20 are responsible for the majority of current pneumococcal disease in adults around the globe. *See* Pfizer Announces Serotypes Included in 20-Valent Pneumococcal Conjugate Vaccine Candidate Being Investigated for the Prevention of Invasive Disease and Pneumonia in Adults Aged 18 Years and Older, PFIZER, https://investors.pfizer.com/investor-news/press-release-details/2019/Pfizer-Announces-Serotypes-Included-in-20-Valent-Pneumococcal-Conjugate-Vaccine-Candidate-Being-Investigated-for-the-Prevention-of-Invasive-Disease-and-Pneumonia-in-Adults-Aged-18-Years-and-Older/default.aspx (last visited Feb. 22, 2021).

II. MERCK'S CHALLENGES TO WYETH'S PNEUMOCOCCAL VACCINE PATENTS

29. Wyeth has applied for and obtained patents around the world related to multivalent pneumococcal conjugate vaccine compositions, including the '060 patent, the '024 patent, the '999 patent, and foreign counterparts thereof.

30. Beginning at least as early as 2012, Merck initiated proceedings challenging Wyeth's pneumococcal conjugate vaccine patents in the United States, the European Union, the United Kingdom, Australia, Canada, Chile, Korea, Japan, China, India, and Russia. Many of these proceedings are currently ongoing.

III. MERCK'S PETITIONS FOR *INTER PARTES* REVIEW OF WYETH'S PNEUMOCOCCAL VACCINE PATENTS

31. In March 2017, Merck filed two post-grant review ("PGR") petitions and three IPR petitions seeking to invalidate all claims of the '060 patent. *See* Petition for Post Grant Review, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, PGR2017-00016 (P.T.A.B. Mar. 22, 2017); Petition for Post Grant Review, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, PGR2017-00017 (P.T.A.B. Mar. 24, 2017); Petition for *Inter Partes* Review, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, No. IPR2017-01211 (P.T.A.B. Mar. 30, 2017); Petition for *Inter Partes* Review, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, No. IPR2017-01215 (P.T.A.B. Mar. 30, 2017); Petition for *Inter Partes* Review, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, No. IPR2017-01223 (P.T.A.B. Mar. 31, 2017). The Patent Trial and Appeal Board ("PTAB") denied instituting trial in all of these proceedings. In the two PGR proceedings, the PTAB held that Merck had not demonstrated that the '060 patent was eligible for post grant review. *See* Decision Denying Institution of PGR, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, PGR2017-00016 (P.T.A.B. Oct. 20, 2017); Decision Denying Institution of PGR, *Merck Sharp & Dohme*

Corp. v. Wyeth LLC, PGR2017-00017 (P.T.A.B. Oct. 20, 2017). In the three IPR proceedings, the PTAB held that Merck had not established a reasonable likelihood that it would prevail in showing that any claim of the '060 patent was unpatentable. *See* Decision Denying Institution of IPR, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-01211 (P.T.A.B Oct. 20, 2017); Decision Denying Institution of IPR, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-01215 (P.T.A.B Oct. 20, 2017); Decision Denying Institution of IPR, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-01223 (P.T.A.B Oct. 20, 2017).

32. Also in March 2017, Merck filed an IPR petition seeking to invalidate all claims of the '024 patent. *See* Petition for *Inter Partes* Review, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-01194 (P.T.A.B. Mar. 29, 2017). The PTAB denied instituting trial in this proceeding. The PTAB held that Merck had not established a reasonable likelihood that it would prevail in showing that any claim of the '024 patent was unpatentable. *See* Decision Denying Institution of IPR, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-01194 (P.T.A.B. Oct. 20, 2017).

33. In December 2016, Merck filed IPR petitions seeking to invalidate certain claims of the '999 patent. *See* Petition for *Inter Partes* Review, *Merck Sharp & Dohme Corp. v. Wyeth LLC et. al.*, IPR2017-00390 (P.T.A.B. Dec. 2, 2016); Petition for *Inter Partes* Review, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-00378 (P.T.A.B. Dec. 2, 2016); Petition for *Inter Partes* Review, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-00380 (P.T.A.B. Dec. 2, 2016). In the two actions that included challenges against Claim 18 of the '999 patent (IPR2017-00378, IPR2017-00380), the PTAB twice upheld Claim 18, both in a first Final Written Decision dated June 8, 2018 and again after a remand from the U.S. Court of Appeals for the Federal Circuit in a second Final Written Decision dated November 5, 2020. *See* Final Written Decision,

Merck Sharp & Dohme Corp. v. Wyeth LLC, IPR2017-00378 (P.T.A.B. June 8, 2018); Final Written Decision, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-00380 (P.T.A.B. June 8, 2018); Final Written Decision, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-00378 (P.T.A.B. Nov. 5, 2020); Final Written Decision, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, IPR2017-00380 (P.T.A.B. Nov. 5, 2020). The November 5, 2020 final written decisions in IPR2017-00378 and IPR2017-00380 are currently the subject of an appeal in the Federal Circuit. *See Merck Sharp & Dohme Corp. v. Wyeth LLC*, No. 21-1453 (Fed. Cir. Dec. 22, 2020).

IV. MERCK'S V114 VACCINE

34. In November 2020, Merck announced that it had submitted a BLA to the FDA for V114, which the head of global clinical development Dr. Roy Barnes stated brought Merck "closer to offering more options to help protect against pneumococcal disease." *See* Merck Submits Applications for Licensure of V114, the Company's Investigational 15-valent Pneumococcal Conjugate Vaccine, for Use in Adults to the U.S. FDA and European Medicines Agency, MERCK, https://www.merck.com/news/merck-submits-applications-for-licensure-of-v114-the-companys-investigational-15-valent-pneumococcal-conjugate-vaccine-for-use-in-adults-to-the-u-s-fda-and-european-medicines-agency/ (last visited Feb. 22, 2021). Dr. Barnes represented V114 as a "potentially important option to help protect more adults from invasive pneumococcal disease." *See* U.S. FDA Accepts for Priority Review the Biologics License Application for V114, Merck's Investigational 15-valent Pneumococcal Conjugate Vaccine, for Use in Adults 18 Years of Age and Older, MERCK, https://www.merck.com/news/u-s-fda-accepts-for-priority-review-the-biologics-license-application-for-v114-mercks-investigational-15-valent-pneumococcal-conjugate-vaccine-for-use-in-adults-18-years-of-age-and-

older/#:~:text=%E2%80%9CBuilding%20on%20our%20nearly%2040,who%20are%20at%20increased%20risk (last visited Feb. 22, 2021).

35. On January 12, 2021, Merck announced that FDA had accepted Merck's application for priority review of its BLA for V114. *See* U.S. FDA Accepts for Priority Review the Biologics License Application for V114, Merck's Investigational 15-valent Pneumococcal Conjugate Vaccine, for Use in Adults 18 Years of Age and Older, MERCK, https://www.merck.com/news/u-s-fda-accepts-for-priority-review-the-biologics-license-application-for-v114-mercks-investigational-15-valent-pneumococcal-conjugate-vaccine-for-use-in-adults-18-years-of-age-and-older/#:~:text=%E2%80%9CBuilding%20on%20our%20nearly%2040,who%20are%20at%20increased%20risk (last visited Feb. 22, 2021).

36. On information and belief, when FDA accepted for priority review Merck's BLA for V114, it set a target action date for July 18, 2021. *See* Complaint for Declaratory Judgment of Invalidity and Non-infringement ¶¶ 5, 31 (Jan. 11, 2021), D.I. 1. Upon FDA approval of Merck's priority application, Merck may commercialize its V114 vaccine in the United States. *See* Types of Applications, Biologic License Application (BLA), FDA, https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications (last visited Feb. 22, 2021) (noting that upon approval of the license, a license issues and the manufacturer may market the product).

37. On information and belief, the fifteen serotypes in V114 are serotypes 22F and 33F in addition to the thirteen serotypes in Prevnar13®. Unlike Merck's pneumococcal vaccine Pneumovax®23, V114 is a polysaccharide-protein conjugate vaccine like Prevnar13®.

38. On information and belief, Merck has conducted a series of Phase II and Phase III clinical trials investigating the safety, tolerability, and immunogenicity of V114, wherein the Phase III clinical program includes 16 trials in a variety of populations who are at increased risk for pneumococcal disease.

39. On information and belief, Merck contends that V114 is a "real alternative" to the existing Pfizer PCVs. *See* Complaint for Declaratory Judgment of Invalidity and Non-infringement ¶ 4 (Jan. 11, 2021), D.I. 1.

40. On information and belief, Merck announced to investors at its June 20, 2019 Investor Day that the V114 vaccine will be Merck's "first foray into the conjugated market." *See* Edited Transcript, Merck & Co Inc. Investor Day, at 17, THOMAS REUTERS STREETEVENTS, https://s21.q4cdn.com/488056881/files/doc_downloads/transcripts/2019/07/MRK-USQ_Transcript_2019-06-20-(2).pdf (last visited Feb. 22, 2021).

41. On information and belief, Merck intends to "use and leverage the entirety of [their] portfolio," including V114, "to meet the distinct needs of markets around the world." *See* Edited Transcript, MRK - Merck & Co Inc. Investor Day, at 17, THOMAS REUTERS STREETEVENTS, https://s21.q4cdn.com/488056881/files/doc_downloads/transcripts/2019/07/MRK-USQ_Transcript_2019-06-20-(2).pdf (last visited Feb. 22, 2021).

42. On Merck's most recent February 4, 2021 Earnings Call, it referred to V114 as part of the "entire pneumococcal franchise that [Merck is] building." *See* Merck & Co., Inc. (MRK) CEO Ken Frazier on Q4 2020 Results – Earning Call Transcript, SEEKING ALPHA$^{\alpha}$, https://seekingalpha.com/article/4403435-merck-co-inc-mrk-ceo-ken-frazier-on-q4-2020-results-earnings-call-transcript (last visited Feb. 22, 2021).

43. On information and belief, Merck has pursued the clinical development of V114 with the goal of offering it for sale and selling it in the United States and other countries.

44. On information and belief, Merck's current preparations for the commercial launch of V114 at least include manufacturing V114 for the U.S. market. On information and belief, Merck would begin manufacturing and/or importing V114 for commercial sale at least several months in advance of an anticipated FDA approval date, *i.e.*, in the months leading up to July 2021. Thus, on information and belief, Merck's manufacture, use, offer for sale, and/or importation of V114 has already begun or is imminent.

45. Merck has, inter alia, "made substantial investments in developing and bringing its V114 vaccine to market and plans to continue investing in V114," including hiring "new employees to bring V114 to market, including employees dedicated to working on the development and manufacture of V114. Merck has made and will continue to make these significant investments in preparation for obtaining expected FDA approval by July 2021." *See* Complaint for Declaratory Judgment of Invalidity and Non-infringement ¶ 35 (Jan. 11, 2021), D.I. 1.

46. In sum, Merck has made actual and real preparations to commercialize V114 in the United States. On information and belief, Merck intends to sell V114 in the United States based on the FDA's approval of its BLA. Merck's manufacture, use, sale, and offer for sale within the United States, and/or importation into the United States, of V114 infringes Counterclaim Plaintiffs' '024, '060, '999, and '681 patents.

47. On July 16, 2021, Merck announced that the FDA had approved V114 for use in adults 18 years of age or older. *See* Merck Announces U.S. FDA Approval of VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) for the Prevention of

Invasive Pneumococcal Disease in Adults 18 Years and Older Caused by 15 Serotypes, MERCK, https://www.merck.com/news/merck-announces-u-s-fda-approval-of-vaxneuvance-pneumococcal-15-valent-conjugate-vaccine-for-the-prevention-of-invasive-pneumococcal-disease-in-adults-18-years-and-older-caused-by-15-serot/ (last visited July 26, 2021).

48. With only one month separating Merck's and Pfizer's FDA approval of their respective next generation pneumococcal vaccines (July 2021 and June 2021, respectively), and the expectation that V114 will compete with Pfizer and Wyeth's PCV vaccines, including its next generation PCV20, the anticipated launch of Merck's V114 vaccine upon approval creates substantial foreseeable irreparable injury for Counterclaim Plaintiffs.

49. Upon offering to sell and selling V114 in the United States, Merck's infringing acts, as described herein, will immediately and irreparably harm Counterclaim Plaintiffs.

COUNT I
(Infringement of the '024 Patent)

50. Each of paragraphs 1-49 above are repeated and re-alleged as if set forth fully herein.

51. On information and belief, Merck has infringed the '024 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c) by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation of V114 prior to the expiration of the '024 patent.

52. V114 and/or its manufacture satisfies each element of, and infringes either literally or under the doctrine of equivalents, at least claim 1 of the '024 patent.

53. Claim 1 of the '024 patent reads: "A multivalent immunogenic composition comprising 13 distinct polysaccharide-protein conjugates and a physiologically acceptable vehicle, wherein each of the conjugates comprises a capsular polysaccharide from a different serotype of *Streptococcus pneumoniae* conjugated to a carrier protein, wherein the serotypes

consist essentially of 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F, and wherein the carrier protein is CRM_{197}." '024 patent, col.35, ll.4-11.

54. On information and belief, Merck has developed V114, which is a 15-valent pneumococcal conjugate vaccine that purportedly contains 15 serotypes each conjugated to a CRM_{197} carrier protein. The 15 serotypes included in the vaccine are: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F. *See, e.g.*, V114 Clinical Program Overview, MERCK, https://www.merck.com/wp-content/uploads/sites/5/2020/11/Factsheet_11.20.20.pdf (last visited Jan. 25, 2021); Merck Submits Applications for Licensure of V114, the Company's investigational 15-valent Pneumococcal Conjugate Vaccine, for Use in Adults to the U.S. FDA and European Medicines Agency, MERCK, https://www.merck.com/news/merck-submits-applications-for-licensure-of-v114-the-companys-investigational-15-valent-pneumococcal-conjugate-vaccine-for-use-in-adults-to-the-u-s-fda-and-european-medicines-agency/ (last visited Feb. 26, 2020).

55. Merck had knowledge of the '024 patent during the development of V114 and when it submitted its BLA for V114 to FDA.

56. Counterclaim Plaintiffs will be substantially and irreparably harmed if Merck is not enjoined from infringing the '024 patent.

57. Counterclaim Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the '060 Patent)

58. Each of paragraphs 1-57 above are repeated and re-alleged as if set forth fully herein.

59. On information and belief, Merck has infringed the '060 patent, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation of V114 prior to the expiration of the '060 patent.

60. V114 and/or its manufacture satisfies each element of, and infringes either literally or under the doctrine of equivalents, at least claim 1 of the '060 patent.

61. Claim 1 of the '060 patent reads: "A multivalent immunogenic composition comprising polysaccharide-protein conjugates and a physiologically acceptable vehicle, wherein each of the conjugates comprises a capsular polysaccharide from a different serotype of *Streptococcus pneumoniae* conjugated to a carrier protein, wherein the serotypes comprise 4, 6B, 9V, 14, 18C, 19F, 23F and at least one additional serotype, wherein the additional serotype is serotype 3, and wherein the carrier protein is CRM_{197}." '060 patent, col.35, ll.16-23.

62. On information and belief, Merck has developed the V114 vaccine, which is a 15-valent pneumococcal conjugate vaccine that purportedly contains 15 serotypes each conjugated to a CRM_{197} carrier protein. The 15 serotypes included in the vaccine are: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F. *See, e.g.*, V114 Clinical Program Overview, MERCK, https://www.merck.com/wp-content/uploads/sites/5/2020/11/Factsheet_11.20.20.pdf (last visited Jan. 25, 2021); Merck Submits Applications for Licensure of V114, the Company's investigational 15-valent Pneumococcal Conjugate Vaccine, for Use in Adults to the U.S. FDA and European Medicines Agency, MERCK, https://www.merck.com/news/merck-submits-applications-for-licensure-of-v114-the-companys-investigational-15-valent-pneumococcal-conjugate-vaccine-for-use-in-adults-to-the-u-s-fda-and-european-medicines-agency/ (last visited Feb. 26, 2020).

63. Merck had knowledge of the '060 patent during the development of V114 and when it submitted its BLA for V114 to FDA.

64. Counterclaim Plaintiffs will be substantially and irreparably harmed if Merck is not enjoined from infringing the '060 patent.

65. Counterclaim Plaintiffs have no adequate remedy at law.

COUNT III
(Infringement of the '999 Patent)

66. Each of paragraphs 1-65 above are repeated and re-alleged as if set forth fully herein.

67. On information and belief, Merck has infringed the '999 patent, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) by engaging in the commercial manufacture, use, offer to sell, sale, and/or importation of V114 prior to the expiration of the '999 patent.

68. V114 and/or its manufacture satisfies each element of, and infringes either literally or under the doctrine of equivalents, at least claim 18 of the '999 patent.

69. Claim 18 depends from Claim 1 of the '999 patent.

70. Claim 1 of the '999 patent reads: "A formulation comprising (i) a pH buffered saline solution, wherein the buffer has a pKa of about 3.5 to about 7.5, (ii) an aluminum salt and (iii) one or more polysaccharide-protein conjugates, wherein the formulation is comprised in a siliconized container means and inhibits aggregation induced by the siliconized container means." '999 patent, col.31, ll.7-12.

71. Claim 18 of the '999 patent reads: "The formulation of claim 1, wherein the one or more polysaccharide-protein conjugate comprises an *S. pneumoniae* serotype 4 polysaccharide conjugated to a CRM_{197} polypeptide, an *S. pneumoniae* serotype 6B polysaccharide conjugated to a CRM_{197} polypeptide, an *S. pneumoniae* serotype 9V polysaccharide conjugated to a CRM_{197}

polypeptide, an *S. pneumoniae* serotype 14 polysaccharide conjugated to a CRM_{197} polypeptide, an *S. pneumoniae* serotype 18C polysaccharide conjugated to a CRM_{197} polypeptide, an *S. pneumoniae* serotype 19F polysaccharide conjugated to a CRM_{197} polypeptide, an *S.pneumoniae* serotype 23F polysaccharide conjugated to a CRM_{197} polypeptide, an *S. pneumoniae* serotype 1 polysaccharide conjugated to a CRM_{197} polypeptide, an *S. pneumoniae* serotype 3 polysaccharide conjugated to a CRM_{197} polypeptide, an *S. pneumoniae* serotype 5 polysaccharide conjugated to a CRM_{197} polypeptide, an *S. pneumoniae* serotype 6A polysaccharide conjugated to a CRM_{197} polypeptide, an *S. pneumoniae* serotype 7F polysaccharide conjugated to a CRM_{197} polypeptide and an *S. pneumoniae* serotype 19A polysaccharide conjugated to a CRM_{197} polypeptide." '999 patent, col.32, ll.24-45.

72. On information and belief, Merck has developed the V114 vaccine, which is a 15-valent pneumococcal conjugate vaccine that purportedly contains 15 serotypes each conjugated to a CRM_{197} carrier protein. The 15 serotypes included in the vaccine are: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F. *See, e.g.*, V114 Clinical Program Overview, MERCK, https://www.merck.com/wp-content/uploads/sites/5/2020/11/Factsheet_11.20.20.pdf (last visited Jan. 25, 2021); Merck Submits Applications for Licensure of V114, the Company's investigational 15-valent Pneumococcal Conjugate Vaccine, for Use in Adults to the U.S. FDA and European Medicines Agency, MERCK, https://www.merck.com/news/merck-submits-applications-for-licensure-of-v114-the-companys-investigational-15-valent-pneumococcal-conjugate-vaccine-for-use-in-adults-to-the-u-s-fda-and-european-medicines-agency/ (last visited Feb. 26, 2020).

73. On information and belief, Merck's V114 vaccine formulation contains a pH buffered saline solution, wherein the buffer has a pKa of about 3.5 to about 7.5, and an aluminum salt.

74. On information and belief, Merck's V114 vaccine formulation is to be sold in a siliconized container.

75. Merck had knowledge of the '999 patent during the development of V114 and when it submitted its BLA for V114 to FDA.

76. Counterclaim Plaintiffs will be substantially and irreparably harmed if Merck is not enjoined from infringing the '999 patent.

77. Counterclaim Plaintiffs have no adequate remedy at law.

COUNT IV
(Infringement of the '681 Patent)

78. Each of paragraphs 1-77 above are repeated and re-alleged as if set forth fully herein.

79. On information and belief, Merck has infringed the '681 patent, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) by engaging in the commercial manufacture of V114 prior to the expiration of the '681 patent.

80. The manufacture of V114 satisfies each element of, and infringes either literally or under the doctrine of equivalents, at least claim 1 of the '681 patent.

81. Claim 1 of the '681 patent reads: "A solution containing substantially purified *Streptococcus pneumoniae* capsular polysaccharide wherein the percent ratio of protein to polysaccharide (protein/PS) is less than 10%, and wherein said polysaccharide has a molecular weight of at least 275,000 daltons." '681 patent, col.28, ll.2-6.

82. On information and belief, Merck has developed the V114 vaccine, which is a 15-valent pneumococcal conjugate vaccine that purportedly contains 15 *Streptococcus pneumoniae* serotypes each conjugated to a CRM_{197} carrier protein. The 15 serotypes included in the vaccine are: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F. *See, e.g.*, V114 Clinical Program Overview, MERCK, https://www.merck.com/wp-content/uploads/sites/5/2020/11/Factsheet_11.20.20.pdf (last visited Jan. 25, 2021); Merck Submits Applications for Licensure of V114, the Company's investigational 15-valent Pneumococcal Conjugate Vaccine, for Use in Adults to the U.S. FDA and European Medicines Agency, MERCK, https://www.merck.com/news/merck-submits-applications-for-licensure-of-v114-the-companys-investigational-15-valent-pneumococcal-conjugate-vaccine-for-use-in-adults-to-the-u-s-fda-and-european-medicines-agency/ (last visited Feb. 26, 2020).

83. On information and belief and according to documents produced by Merck in this action, the manufacture of V114 includes making and using a solution containing substantially purified *Streptococcus pneumoniae* capsular polysaccharide for each polysaccharide serotype contained in V114.

84. On information and belief and according to documents produced by Merck in this action, the manufacture of V114 includes making and using at least one solution containing substantially purified *Streptococcus pneumoniae* capsular polysaccharide, where the percent ratio of protein to polysaccharide (protein/PS) in the solution is less than 10% and the molecular weight of the polysaccharide is at least 275,000 daltons.

85. Merck had knowledge of the '681 patent at least as of the date of these amended counterclaims.

86. Counterclaim Plaintiffs will be substantially and irreparably harmed if Merck is not enjoined from infringing the ’681 patent.

87. Counterclaim Plaintiffs have no adequate remedy at law.

COUNT V
(Declaratory Judgment of Infringement of the ’024 Patent)

88. Each of paragraphs 1-87 above are repeated and re-alleged as if set forth fully herein.

89. On information and belief, FDA’s approval of Merck’s BLA to market V114 in the United States, coupled with Merck’s preparations to launch V114 for sale to the domestic marketplace upon receiving that approval, creates an actual, immediate, and real controversy under the Declaratory Judgment Act that Merck will directly or indirectly infringe valid and enforceable claims of the ’024 patent.

90. On information and belief, Merck does or will infringe at least claim 1 of the ’024 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c) literally or under the doctrine of equivalents, by making, using, selling, and/or offering to sell in the United States without authority and/or importing into the United States without authority the V114 vaccine.

91. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

92. Counterclaim Plaintiffs will be substantially and irreparably harmed if Merck is not enjoined from infringing the ’024 patent.

93. Counterclaim Plaintiffs have no adequate remedy at law.

COUNT VI
(Declaratory Judgment of Infringement of the '060 Patent)

94. Each of paragraphs 1-93 above are repeated and re-alleged as if set forth fully herein.

95. On information and belief, FDA's approval of Merck's BLA to market V114 in the United States, coupled with Merck's preparations to launch V114 for sale to the domestic marketplace upon receiving that approval, creates an actual, immediate, and real controversy under the Declaratory Judgment Act that Merck will directly or indirectly infringe valid and enforceable claims of the '060 patent.

96. On information and belief, Merck does or will infringe at least claim 1 of the '060 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c) literally or under the doctrine of equivalents, by making, using, selling, and/or offering to sell in the United States without authority and/or importing into the United States without authority the V114 vaccine.

97. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

98. Counterclaim Plaintiffs will be substantially and irreparably harmed if Merck is not enjoined from infringing the '060 patent.

99. Counterclaim Plaintiffs have no adequate remedy at law.

COUNT VII
(Declaratory Judgment of Infringement of the '999 Patent)

100. Each of paragraphs 1-99 above are repeated and re-alleged as if set forth fully herein.

101. On information and belief, FDA's approval of Merck's BLA to market V114 in the United States, coupled with Merck's preparations to launch V114 for sale to the domestic

marketplace upon receiving that approval, creates an actual, immediate, and real controversy under the Declaratory Judgment Act that Merck will directly or indirectly infringe valid and enforceable claims of the '999 patent.

102. On information and belief, Merck does or will infringe at least claim 18 of the '999 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c) literally or under the doctrine of equivalents, by making, using, selling, and/or offering to sell in the United States without authority and/or importing into the United States without authority the V114 vaccine.

103. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

104. Counterclaim Plaintiffs will be substantially and irreparably harmed if Merck is not enjoined from infringing the '999 patent.

105. Counterclaim Plaintiffs have no adequate remedy at law.

COUNT VIII
(Declaratory Judgment of Infringement of the '681 Patent)

106. Each of paragraphs 1-105 above are repeated and re-alleged as if set forth fully herein.

107. On information and belief, FDA's approval of Merck's BLA to market V114 in the United States, coupled with Merck's preparations to launch V114 for sale to the domestic marketplace upon receiving that approval, creates an actual, immediate, and real controversy under the Declaratory Judgment Act that Merck will directly or indirectly infringe valid and enforceable claims of the '681 patent.

108. On information and belief, Merck does or will infringe at least claim 1 of the '681 patent pursuant to 35 U.S.C. § 271(a), (b), and/or (c) literally or under the doctrine of

equivalents, by making, using, selling, and/or offering to sell in the United States without authority and/or importing into the United States without authority the V114 vaccine.

109. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

110. Counterclaim Plaintiffs will be substantially and irreparably harmed if Merck is not enjoined from infringing the '681 patent.

111. Counterclaim Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim Plaintiffs pray for judgment against Merck and respectfully request the following relief:

A. A judgment awarding Wyeth the relief it seeks in its Defenses asserted in response to Merck's Complaint for Declaratory Judgment of Invalidity and Non-Infringement;

B. A judgment that the '024 patent has been infringed and will be infringed by Merck, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

C. A judgment that the '060 patent has been infringed and will be infringed by Merck, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

D. A judgment that the '999 patent has been infringed and will be infringed by Merck, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

E. A judgment that the '681 patent has been infringed and will be infringed by Merck, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

F. A judgment for an injunction enjoining Merck, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing products that infringe the Patents-in-Suit, including the V114 vaccine, prior to the expiration of the Patents-in-Suit pursuant to 35 U.S.C. § 283;

G. To the extent that Merck has or will commercially manufacture, use, offer to sell, or sell V114 within the United States or import V114 into the United States, prior to the expiration of the Patents-in-Suit, including any extensions, a judgment awarding Counterclaim Plaintiffs monetary relief pursuant to 35 U.S.C. § 284, together with interest;

H. A judgment finding Merck's infringement of the Patents-in-Suit is willful, and/or an order increasing any damages awarded for Merck's infringement of the Patents-in-Suit pursuant to 35 U.S.C. § 284;

I. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Counterclaim Plaintiffs to an award of their reasonable attorneys' fees for bringing and prosecuting this action;

J. An award of Counterclaim Plaintiffs' costs and expenses in this action;

K. Such further and other relief as this Court deems to be just and proper.

JURY DEMAND

Counterclaim Plaintiffs hereby demand a trial by jury on all such issues so triable.

OF COUNSEL:

Dimitrios T. Drivas
John P. Scheibeler
Amit H. Thakore
C. Sebastian Zonte
Lauren Kuehn Pelletier
WHITE & CASE LLP
1221 Avenue of the Americas
New York, NY 10020
(212) 819-8200

Hallie Kiernan
WHITE & CASE LLP
3000 El Camino Real
Two Palo Alto Square, Suite 900
Palo Alto, CA 94306
(650)-213-0300

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CONNOLLY GALLAGHER LLP

/S/ ARTHUR G. CONNOLLY, III

Arthur G. Connolly, III (#2667)
Brandon R. Harper (#6418)
1201 North Market Street, 20th Floor
Wilmington, DE 19801
(302) 757-7300
(302) 757-7299
aconnolly@connollygallagher.com
bharper@connollygallagher.com

Attorneys for Defendant and Counterclaim Plaintiffs