IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. _____
	)	
WYETH LLC,	)	
	)	
Defendant.	)	

COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY AND NON-INFRINGEMENT

Plaintiff Merck Sharp & Dohme Corp. ("Merck"), by and through its undersigned counsel, and for its complaint against Defendant Wyeth LLC ("Wyeth"), alleges as follows:

INTRODUCTION

1. Merck is a leading global healthcare company that delivers innovative and important health solutions. Merck invests heavily in research and development, spending nearly $10 billion on such activities in 2019 alone. As part of its research, Merck scientists have pioneered the development of novel vaccines to protect against life-threatening illnesses for more than a century. For instance, Merck has developed and obtained approval to market vaccines to prevent diseases such as measles, mumps, and rubella; ebola; human papillomavirus; hepatitis A and B; varicella; and pneumococcus.

2. Importantly, in the 1970s, Merck developed PNEUMOVAX®, its first U.S. Food and Drug Administration ("FDA")-approved pneumococcal vaccine providing protection against 14 strains of bacteria from *Streptococcus pneumoniae* ("*S. pneumoniae*" or "pneumococcus"). Since then, Merck has continued to improve vaccine protection against pneumococcus. In the 1980s, Merck introduced PNEUMOVAX®23, expanding the protection provided by

PNEUMOVAX® to 23 strains of pneumococcus. PNEUMOVAX®23 remains a leading adult pneumococcal vaccine on the market today with over 22 million doses distributed annually worldwide.

3. Presently, Merck is seeking FDA-approval for a new, different type of pneumococcal vaccine, known as V114. PNEUMOVAX®23 is a "pneumococcal **polysaccharide** vaccine" (or "PPSV"), whereas V114 is known as a "pneumococcal **conjugate** vaccine" (or "PCV"). As explained in greater detail below, for some populations, particularly children under two years old, PCVs create a more robust immune response than PPSVs.

4. Until now, Wyeth has been alone in the U.S. market for PCVs, first with its vaccine called Prevnar® (covering 7 pneumococcus strains) and then for the last decade, with Prevnar 13® (covering 13 strains). But, Merck's new V114 now presents a real alternative to Wyeth's PCVs. V114 provides coverage for two additional strains of *S. pneumoniae* over Wyeth's Prevnar 13®, and in a clinical trial in adults, V114 has demonstrated superiority compared to Prevnar 13® with respect to one of the strains common to both V114 and Prevnar 13®.

5. Merck submitted its Biologics License Application ("BLA")[1] for FDA approval of V114 on November 17, 2020, having completed all necessary pre-clinical and clinical development trials of V114, including both Phase II and Phase III clinical trials needed for submission of its application to seek approval to sell and market V114 in the United States. The BLA seeking initial approval for use in adults 18 years of age and older was accepted for FDA review on January 11, 2021 and FDA approval of V114 is anticipated to occur by July 18, 2021

[1] The BLA is the formal request and application filed with FDA to introduce, or deliver for introduction, a biologic product into interstate commerce. *See* 21 C.F.R. § 601.2.

(priority review granted) for its first indication in adults 18 and over for the prevention of invasive pneumococcal disease caused by 15 serotypes of pneumococcus.

6. Merck and Wyeth are embroiled in patent battles around the world in anticipation of regulatory approval of V114. Wyeth (and/or its affiliates) is attempting to maintain Prevnar 13®'s market position through the aggressive pursuit of non-inventive and overly broad interpretations of its pneumococcal conjugate patents, whereas Merck is seeking to deliver its V114 to patients without the cloud of Wyeth's threats of patent infringement. Indeed, there are presently patent disputes between Merck and Wyeth in Australia, Canada, the European Patent Office ("EPO"), Japan, Korea, the Netherlands, the United Kingdom, and here in the United States, among other places.

7. The instant action is being commenced so that Merck can clear the way to deliver V114 to patients in the United States by lifting the threat of an imminent lawsuit by Wyeth for infringement of three United States patents relating to pneumococcal conjugate compositions. Through this lawsuit, Merck will show that V114 does not and will not infringe any valid claim of these three patents.

NATURE OF THIS ACTION

8. This is an 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.*

9. Merck requests a declaratory judgment that U.S. Patent Nos. 8,895,024 B2 ("the '024 patent"); 8,808,708 B2 ("the '708 patent"); and 9,399,060 B2 ("the '060 patent") (collectively, "the patents-in-suit") are either invalid, not infringed, or both. Specifically, Merck seeks a declaration that no valid claim of any of the '024, '708, or '060 patents will be infringed by Merck's V114, once it is made, used, offered for sale, or sold within the United States or imported into the United States within the meaning of 35 U.S.C. § 271. Pursuant to the Local

Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, true and correct copies of the '024 patent, '708 patent, and '060 patent are attached hereto as Exhibits A, B, and C, respectively. D. Del. LR 3.2.

10. A finding by this Court that the claims of the patents-in-suit are invalid and/or not infringed would finally and conclusively resolve the dispute between the parties concerning whether any claims of the patents-in-suit are valid or infringed.

THE PARTIES

11. 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. As part of its business, Merck is involved in the research, development, and marketing of novel life-saving medicines including prescription pharmaceutical products and vaccines. 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.

12. Wyeth is a Delaware limited liability company having its principal place of business at 235 East 42nd Street, New York, New York 10017. Wyeth is a wholly owned subsidiary of Pfizer Inc. ("Pfizer").

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction in this case pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 because this is a civil action requesting a declaratory judgment by the Court and arises under the patent laws of the United States.

14. This Court has general personal jurisdiction over Wyeth because, *inter alia*, Wyeth is a Delaware limited liability company.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b). Wyeth is subject to personal jurisdiction in this judicial district, and thus it resides in this judicial district under 28 U.S.C. § 1391(c). In addition, venue is proper in this judicial district because Wyeth is incorporated in Delaware.

FACTUAL BACKGROUND

I. PNEUMOCOCCAL VACCINE TECHNOLOGY

16. This case concerns pneumococcal vaccines. Such vaccines are administered to persons of all ages to protect against various infectious diseases, like meningitis and pneumonia, caused by the bacterium *S. pneumoniae*. Pneumococcal vaccines come in two primary forms: pneumococcal conjugate vaccines ("PCV") and pneumococcal polysaccharide vaccines ("PPSV"). PPSV are also called "unconjugated" vaccines.

17. Both conjugated and unconjugated vaccines contain large molecules called polysaccharides that are taken from different strains, or "serotypes," of *S. pneumoniae* bacteria. There are presently approximately 100 known serotypes of *S. pneumoniae*. Each serotype is a bacterial cell that is classified by its particular coating or covering ("capsule") of polysaccharides, which are repeating units of sugar. The capsular polysaccharides are a major source of virulence for the bacteria, enabling bacteria to adhere to their environment and cause infections. These capsular polysaccharides are used in pneumococcal vaccines to cause a patient's immune system to develop antibodies that will, in the future, recognize that polysaccharide. In this way, the immune system is "taught" to recognize and destroy a specific *S. pneumoniae* bacteria serotype before it causes disease.

18. Merck is a pioneer in the development of pneumococcal vaccines, having developed its first such vaccine approved by the FDA in the 1970s.

19. That vaccine was approved in 1977. It was a 14-valent PPSV known as PNEUMOVAX®. Thereafter, Merck developed an improved PPSV vaccine, and received FDA approval for a more robust 23-valent PPSV, PNEUMOVAX®23, in 1983. PNEUMOVAX®23 contains polysaccharides from 23 different serotypes and it is marketed around the world for the prevention of pneumococcal diseases.

20. Despite the successful use of PPSVs to immunize adults and older children, studies have shown that PPSVs are poorly immunogenic in children younger than two years old. In order to enhance the body's innate immune response and create immunity in younger children, bacterial polysaccharides like the *S. pneumoniae* polysaccharides can be conjugated (or attached)[2] to a carrier protein.

21. One well-known example of a carrier protein is CRM_{197}, a nontoxic modified form of diphtheria toxin. CRM_{197} has been used since as early as the 1980s to create conjugate vaccines, and it continues to be widely used in conjugate vaccines, including vaccines to protect against disease caused by *Haemophilus influenzae* type b (*Hib*), meningococcal disease, and pneumococcal disease.

22. Vaccine manufacturers have successfully incorporated CRM_{197} and other carrier proteins to produce more effective pneumococcal vaccine products. Prevnar® (or Prevenar in some parts of the world), a 7-valent PCV developed by Wyeth, became the first PCV approved for sale in the United States in 2000. Additional PCVs have entered the market since that time. For example, Wyeth introduced a 13-valent PCV in 2010 called Prevnar 13®, (or Prevenar 13 in some parts of the world) and GlaxoSmithKline markets a 10-valent PCV, Synflorix™, that is

[2] Conjugation refers to the covalent attachment between two or more molecules. In the case of pneumococcal conjugate vaccines, bacterial capsular polysaccharides from *S. pneumoniae* are covalently bonded to carrier protein.

approved in the UK and registered in parts of Europe and Japan. With Prevnar® and Prevnar 13®, Wyeth has enjoyed exclusivity in the PCV market in the United States for 20 years.

II. MERCK'S AND WYETH'S PNEUMOCOCCAL VACCINES

23. Merck has a long history of researching, discovering, developing, and manufacturing vaccines. For more than a century, Merck and its predecessor companies have worked to discover and develop an array of vaccines to prevent a variety of diseases.

24. Some of the vaccines that Merck has developed and sold include:

(i) BCG Vaccine (for percutaneous use);

(ii) ERVEBO® (Ebola Zaire Vaccine, Live);

(iii) GARDISIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant);

(iv) M-M-R®II (Measles, Mumps, and Rubella Virus Vaccine, Live);

(v) Liquid PedvaxHIB® (Haemophilus b Conjugate Vaccine [Meningococcal Protein Conjugate]);

(vi) PNEUMOVAX®23 (Pneumococcal Vaccine Polyvalent);

(vii) ProQuad® (Measles, Mumps, Rubella, and Varicella Virus Vaccine, Live);

(viii) RECOMBIVAX HB® (Hepatitis B Vaccine, Recombinant);

(ix) RotaTeq® (Rotavirus Vaccine, Live, Oral, Pentavalent);

(x) VAQTA® (Hepatitis A Vaccine, Inactivate);

(xi) VARIVAX® (Varicella Virus Vaccine, Live); and

(xii) ZOSTAVAX® (Zoster Vaccine, Live).

25. As discussed above, Merck developed its first ever licensed PPSV in the 1970s, and it continues to manufacture and distribute its improved PPSV, PNEUMOVAX®23, around the world today. PNEUMOVAX®23 contains polysaccharides from 23 *S. pneumoniae*

serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F. The FDA initially approved PNEUMOVAX®23 in 1983.

26. Prevnar®, Wyeth's 7-valent PCV approved in 2000, included the serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F, each individually conjugated to CRM_{197}. Prevnar 13® is a 13-valent PCV and includes the serotypes found Prevnar® plus 6 additional serotypes—serotypes 1, 3, 5, 6A, 7F, and 19A—each individually conjugated to CRM_{197}.

27. Pfizer and/or its affiliates currently market Prevnar 13®, which is manufactured by Wyeth and/or its affiliates.

28. Merck has pursued and still is pursuing its own novel and beneficial PCVs. For example, Merck researched and developed a 15-valent PCV, to, *inter alia*, improve upon the existing lower valent PCVs. Merck has designated its 15-valent PCV as "V114." V114 contains the capsular polysaccharides contained in Prevnar 13® plus two additional serotype conjugates, 22F and 33F, each individually conjugated to CRM_{197}. Importantly, as of late 2020, serotype 22F and serotype 33F still caused 13 percent of the invasive pneumococcal disease among U.S. adults aged 65 and older, and seven to 12 percent of the adult cases across Europe. Yet, no PCV on the market to date contains conjugates of 22F or 33F. Thus, the inclusion of these two additional serotypes expands the coverage afforded by V114 over any other available PCV. Furthermore, Merck's V114 has also been shown to induce a more robust antibody response against serotype 3 than the currently available Prevnar 13®.

III. MERCK V114 ANTICIPATED FDA APPROVAL

29. Merck's Phase III clinical development program involves 16 trials to investigate the safety, tolerability, and immunogenicity of V114 in variety of populations who are at increased risk for pneumococcal disease, including healthy older adults and children, as well as people who are immunocompromised or have certain chronic medical conditions. An overview

of the late-stage development program is available at https://www.merck.com/wp-content/uploads/sites/5/2020/11/Factsheet_11.20.20.pdf (last visited 1/11/2021).

30. Merck's Phase III trials confirmed and expanded upon the prior Phase I and Phase II trials. For instance, the pivotal Phase III study (V114-019) in healthy adults over 50, demonstrated that V114 is non-inferior to Prevnar 13® for the shared serotypes, had superior immunogenicity for the shared serotype 3, and had superior immunogenicity for the two serotypes not found in Prevnar 13®. In another Phase III study (V114-020), V114 elicited an equivalent immune response across all 15 serotypes for three different lots. These results are significant for patients and the scientific community. (Merck's V114 clinical trials and some of their associated results can be found at https://clinicaltrials.gov).

31. Data from the completed clinical trials needed for submission of Merck's application for FDA approval was submitted to the FDA on November 17, 2020 and accepted for review by the FDA on January 11, 2021. Under the Prescription Drug User Fee Act and amendments thereto, the target date for expected approval of Merck's BLA for its initial indication in adults 18 and over is by July 18, 2021.

32. Merck is continuing to conduct Phase III clinical trials to support additional indications in other populations (such as children 6 weeks to under 18 years old and adults at increased risk for pneumococcal disease).

33. Merck received Breakthrough Therapy designations from the FDA for the prevention of pneumococcal disease by V114 in both pediatric patients and adults. Such designation is "designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant

endpoint(s)." BREAKTHROUGH THERAPY, https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy (last visited 1/11/2021). The designation makes a drug eligible for: (1) "All Fast Track designation features"; (2) "Intensive guidance on an efficient drug development program, beginning as early as Phase I"; (3) and "Organizational commitment involving senior managers." *Id.*

34. Merck plans to submit an application to the FDA for market approval of V114 in the pediatric population as well.

35. Merck has made substantial investments in developing and bringing its V114 vaccine to market and plans to continue investing in V114. Indeed, Merck has 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. Merck has made and will continue to make these significant investments in preparation for obtaining expected FDA approval by July 2021. The medical community is awaiting the approval of this vaccine advancement.

IV. WYETH'S PATENTS

36. Wyeth maintains a portfolio of patents relating to pneumococcal vaccines, including the patents-in-suit.

37. The '024 patent is titled "Multivalent Pneumococcal Polysaccharide-Protein Conjugate Composition," lists a filing date of January 22, 2009, lists an issue date of November 25, 2014, and lists Wyeth as the assignee.

38. The '708 patent is titled "Multivalent Pneumococcal Polysaccharide-Protein Conjugate Composition," lists a filing date of April 4, 2012, lists an issue date of August 19, 2014, and lists Wyeth as the assignee.

39. The ’060 patent is titled “Multivalent Pneumococcal Polysaccharide-Protein Conjugate Composition,” lists a filing date of July 2, 2014, lists an issue date of July 26, 2016, and lists Wyeth as the assignee.

40. Wyeth owns foreign counterparts to the patents-in-suit (*e.g.*, AU Patent Nos. 2006235013 and 2013206844, CA Patent No. 2604363, EP Patent No. 1868645 B1 (now revoked), JP Patent Nos. 4472770 and 5173920, and Korean Patent No. 1298053, (collectively the “Foreign Composition Patents”)) as well as related patents that claim: (a) various formulations and containers for 13-valent PCVs (*e.g.*, U.S. Patent Nos. 7,935,787 and 8,562,999; AU Patent No. 2012216628; CA Patent Nos. 2650056 and 2803111; EP Patent No. 2676679; JP Patent No. 6192115; and KR Patent Nos. 1514913 and 1514847; collectively the “Formulation & Container Patents”); and (b) methods of preparing conjugates used in the PCVs (*e.g.*, KR Patent No. 1588939, the “Conjugate Patents”). As foreign counterparts to the patents-in-suit, the Foreign Composition Patents contain claims that are similar to those of the patents-in-suit. Wyeth’s patents-in-suit, Foreign Composition Patents, Formulation & Container Patents, and Conjugate Patents are collectively referred to herein as Wyeth’s PCV Patents.

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

41. For more than four years, Merck and Wyeth have been embroiled in extensive patent infringement and invalidity proceedings around the globe involving a number of Wyeth’s PCV Patents—including the Foreign Composition Patents (the foreign counterparts to the patents-in-suit)—and Merck’s V114 vaccine.

42. Merck and Wyeth are, or have been, involved in such proceedings in Australia, Canada, the European Patent Office (“EPO”), Japan, Korea, the Netherlands, the United Kingdom, and here in the United States. These proceedings involve Wyeth’s PCV Patents that

are either counterparts to the patents-in-suit or counterparts to patents that are closely-related to the patents-in-suit.

43. Of particular significance, in legal proceedings in both Australia and the United Kingdom, Wyeth has alleged infringement of Wyeth's PCV Patents by V114. Specifically, in 2017, Wyeth asserted that Merck's V114 vaccine infringes the Australian Foreign Composition Patents and Australian Formulation & Container Patent, stating that "[Merck] ha[s] threatened to infringe" the claims of the Australian Foreign Composition Patents and the Australian Formulation & Container Patent. Wyeth's Statement of Cross-Claim, ¶ 12, *Merck Sharp & Dohme Corp. & Anor v Wyeth LLC* (NSD 1381 of 2017) (November 14, 2017) (Austl.). At that time, Merck had not yet submitted a marketing approval application for V114 in Australia.

44. That Australian action went to trial in 2019. In its Closing Submission at trial, Wyeth confirmed its earlier assertion of infringement by V114, stating:

> As regards the Asserted Composition Patents Claims and claim 18 of the Container Patent, Wyeth submits that [Merck's] admissions are sufficient to establish infringement. [Merck] has threatened to exploit Wyeth's claimed product and claimed method in the patent area during the term of the Patents, such that Wyeth is entitled to *quia timet* relief.

Wyeth's Closing Submission on Infringement, ¶ 45, *Merck Sharp & Dohme Corp. & Anor v Wyeth LLC* (NSD 1381 of 2017) (15 January 2019) (Austl.). In October 2020, the Australian court found two of the three asserted Wyeth patents invalid. The court found that Merck infringes the third, and Merck will appeal that finding.

45. Similarly, in 2019, Wyeth alleged that V114 infringes a UK Formulation & Container Patent, which includes claims that are similar to those in the patents-in-suit. Specifically, Wyeth asserted that:

> The Claimant threatens and intends to, in the United Kingdom and without the consent of the Defendant, import, keep, use, dispose of

> and/or offer to dispose of a pneumococcal vaccine product ("the Claimant's vaccine") which is intended to be the same in all material respects as the V114 product which is the subject of phase III clinical trials being conducted by the Claimant's associated company Merck Sharp & Dohme Corp ("MSD Corp").
>
> …
>
> The Claimant's vaccine is a product falling within the scope of protection of at least claims 1-11 and 14-15 of the Patent.

Merck Sharp & Dohme Ltd. v. Wyeth LLC [2020] EWHC 742, [1], [2] [Particulars of Infringement] (Pat) (UK). In its opening argument for trial, submitted to the High Court of Justice of England and Whales in June 2020, Wyeth stated: "This is a patent trial which concerns conjugated pneumococcal vaccines. The Claimant [Merck Sharp & Dohme Limited] wishes to launch such a vaccine on the UK market which the Defendant [Wyeth LLC] says infringes its patent." *Merck Sharp & Dohme Ltd. v. Wyeth LLC* [2020] EWHC 742, [1] [Wyeth's Opening Trial Skeleton Argument] (Pat) (UK). Trial for the action in the United Kingdom concluded in July 2020. In October 2020, the High Court ruled that the asserted claims of the patent are: (i) limited to a 13-valent composition, and thus that, Merck's 15-valent V114 does not infringe; and (ii) invalid for obviousness.

46. In addition, Merck (and/or its affiliates) and Wyeth (and/or its affiliates) were or are parties to a number of other proceedings around the world relating to the invalidity of Wyeth's PCV Patents, including the Foreign Composition Patents. Those proceedings include:

- an Opposition filed by Merck in the EPO against a Foreign Composition Patent in which the EPO revoked the patent, finding that it lacked inventive step (in essence, it was obvious) over the prior art;
- an Opposition in the EPO against a Formulation & Container Patent;

- an invalidation action filed by Merck in the Netherlands against a Formulation & Container Patent;
- a patent impeachment action filed in Canada related to a Foreign Composition Patent and Formulation & Container Patents;
- several invalidation actions filed with the Japan Patent Office related to Foreign Composition Patents and a Formulation & Container Patent, which are in multiple states of finality;
- several actions filed in South Korea related to Foreign Composition Patents, Formulation & Container Patents, and Conjugate Patents; and
- multiple *inter partes* review and post-grant review proceedings filed at the Patent Trial and Appeal Board of the United States Patent and Trademark Office against some of the patents-in-suit and a Formulation & Container Patent.

47. The legal proceedings around the world involving Wyeth and Merck regarding the validity and/or enforceability of Wyeth's PCV Patents, including Wyeth's multiple allegations of infringement against V114, coupled with Merck's extensive research and development, the submission of its BLA and acceptance for review, and expected imminent regulatory approval for its allegedly infringing V114 vaccine, establish an actual and justiciable controversy between the parties with respect to the patents-in-suit.

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

48. Merck incorporates by reference the allegations set forth in the preceding paragraphs, as if fully set forth herein.

49. Upon information and belief, Wyeth is the owner of the '024 patent and contends that the claims of the '024 patent are valid.

50. The claims of the ’024 patent are invalid at least for failure to comply with the requirements for patentability of Title 35 of the U.S. Code, including but not limited to 35 U.S.C. §§ 102, 103, and 112.

51. By way of example, the claims of the ’024 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in light of US 2006/0228380 (“’380 publication”); Huebner et al., “Long-term antibody levels and booster responses in South African children immunized with nonavalent pneumococcal conjugate vaccine,” VACCINE 22:2696-2700 (2004) (“Huebner 2004”); Hausdorff et al., “Multinational study of pneumococcal serotypes causing acute otitis media in children,” PEDIATR. INFECT. DIS. J. 21(11):1008-1016 (2002) (“Hausdorff 2002”); and the Prevnar® entry from the 2001 (55th Edition) Physicians’ Desk Reference (“Prevnar 2001”); and for at least the reasons set forth in the Petition filed in IPR2017-01194.

52. As a further example, on information and belief, Wyeth contends that one or more claims of the ’024 patent cover PCVs with more than the 13 serotype-conjugates disclosed in the specification (including Merck’s V114 vaccine), as Wyeth has done with the related Foreign Composition Patents. However, the claims of the ’024 patent are invalid for failing to provide an enabling disclosure or adequate written description under 35 U.S.C. § 112.

53. An actual case or controversy exists between Merck and Wyeth as to whether or not any of the claims of the ’024 patent are valid.

54. Declaratory relief is appropriate and necessary to establish that the claims of the ’024 patent are invalid.

55. Pursuant to 28 U.S.C. §§ 2201, *et seq.*, Merck is entitled to a declaratory judgment that the claims of the ’024 patent are invalid.

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

56. Merck incorporates by reference the allegations set forth in the preceding paragraphs, as if fully set forth herein.

57. Upon information and belief, Wyeth is the owner of the '708 patent and contends that the claims of the '708 patent are valid.

58. The claims of the '708 patent are invalid at least for failure to comply with the requirements for patentability of Title 35 of the U.S. Code, including but not limited to 35 U.S.C. §§ 102, 103, and 112.

59. By way of example, the claims of the '708 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in light of the '380 publication, Huebner 2004, Hausdorff 2002, and Prevnar 2001.

60. An actual case or controversy exists between Merck and Wyeth as to whether or not any of the claims of the '708 patent are valid.

61. Declaratory relief is appropriate and necessary to establish that the claims of the '708 patent are invalid.

62. Pursuant to 28 U.S.C. §§ 2201, *et seq.*, Merck is entitled to a declaratory judgment that the claims of the '708 patent are invalid.

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

63. Merck incorporates by reference the allegations set forth in the preceding paragraphs, as if fully set forth herein.

64. Upon information and belief, Wyeth is the owner of the '060 patent and contends that the claims of the '060 patent are valid.

65. The claims of the ’060 patent are invalid at least for failure to comply with the requirements for patentability of Title 35 of the U.S. Code, including but not limited to 35 U.S.C. §§ 102, 103, and 112.

66. By way of example, the claims of the ’060 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in light of the ’380 publication; Sigurdardottir et al., “Immune response to octavalent diphtheria- and tetanus-conjugated pneumococcal vaccines is serotype- and carrier-specific: the choice for a mixed carrier vaccine,” PEDIATR. INFECT. DIS. J. 21:548–54 (2002); Chiron’s International Patent Publication No. WO 03/009869; Wyeth’s International Patent Publication No. WO 2002/083855; Huebner 2004; Hausdorff 2002; Prevnar 2001; and Overturf, “Pneumococcal Vaccination of Children,” SEMIN. PEDIAT. INFEC. DIS. 13(3):155-164 (2002), and for at least the reasons set forth in the Petitions filed in IPR2017-01211, IPR2017-01215, IPR2017-01223, PGR2017-00016, and PGR2017-00017.

67. As a further example, on information and belief, Wyeth contends that one or more claims of the ’060 patent cover PCVs with more than the 13 serotype-conjugates disclosed in the specification (including Merck’s V114 vaccine), as Wyeth has done with the related Foreign Composition Patents. However, the claims of the ’060 patent are invalid for failing to provide an enabling disclosure or adequate written description under 35 U.S.C. § 112.

68. An actual case or controversy exists between Merck and Wyeth as to whether or not any of the claims of the ’060 patent are valid.

69. Declaratory relief is appropriate and necessary to establish that the claims of the ’060 patent are invalid.

70. Pursuant to 28 U.S.C. §§ 2201, *et seq.*, Merck is entitled to a declaratory judgment that the claims of the ’060 patent are invalid.

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

71. Merck incorporates by reference the allegations set forth in the preceding paragraphs, as if fully set forth herein.

72. Upon information and belief, Wyeth is the owner of the ’024 patent and contends that one or more claims of the ’024 patent is or will be infringed by Merck’s V114 vaccine.

73. As described above, the ’024 patent claims pneumococcal conjugate vaccine compositions.

74. Merck contends 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. For instance, Merck contends that no valid claim of the ’024 patent encompasses any PCV of more than 13-valent. Because Merck’s V114 is a 15-valent PCV, it does not and will not infringe any valid and enforceable claim of the ’024 patent.

76. An actual case or controversy exists between Merck and Wyeth as to whether or not any valid claim of the ’024 patent is or will be infringed by Merck’s V114 vaccine.

77. Declaratory relief is appropriate and necessary to establish that the manufacture, use, offer for sale, sale, or importation into the United States of Merck’s V114 vaccine does not and will not infringe, directly or indirectly, any valid and enforceable claim of the ’024 patent under 35 U.S.C. § 271(a), (b), or (c).

78. Pursuant to 28 U.S.C. §§ 2201, *et seq.*, Merck is entitled to a declaratory judgment that V114 does not and will not infringe any valid and enforceable claim of the ’024 patent.

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

79. Merck incorporates by reference the allegations set forth in the preceding paragraphs, as if fully set forth herein.

80. Upon information and belief, Wyeth is the owner of the '708 patent and contends that one or more claims of the '708 patent is or will be infringed by Merck's V114 vaccine.

81. As described above, the '708 patent claims pneumococcal conjugate vaccine compositions.

82. Merck contends 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 '708 patent.

83. For instance, Merck contends that no valid claim of the '708 patent encompasses any PCV of more than 13 valent. Because Merck's V114 is a 15-valent PCV, it does not and will not infringe any valid and enforceable claim of the '708 patent.

84. An actual case or controversy exists between Merck and Wyeth as to whether or not any valid claim of the '708 patent is or will be infringed by Merck's V114 vaccine.

85. Declaratory relief is appropriate and necessary to establish that the manufacture, use, offer for sale, sale, or importation into the United States of Merck's V114 vaccine does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '708 patent under 35 U.S.C. § 271(a), (b), or (c).

86. Pursuant to 28 U.S.C. §§ 2201, *et seq.*, Merck is entitled to a declaratory judgment that V114 does not and will not infringe any valid and enforceable claim of the '708 patent.

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

87. Merck incorporates by reference the allegations set forth in the preceding paragraphs, as if fully set forth herein.

88. Upon information and belief, Wyeth is the owner of the '060 patent and contends that one or more claims of the '060 patent is or will be infringed by Merck's V114 vaccine.

89. As described above, the '060 patent claims pneumococcal conjugate vaccine compositions.

90. Merck contends 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. For instance, Merck contends that no valid claim of the '060 patent encompasses any PCV or more than 13-valent. Because Merck's V114 is a 15-valent PCV, it does not and will not infringe any valid and enforceable claim of the '060 patent.

92. An actual case or controversy exists between Merck and Wyeth as to whether or not any valid claim of the '060 patent is or will be infringed by Merck's V114 vaccine.

93. Declaratory relief is appropriate and necessary to establish that the manufacture, use, offer for sale, sale, or importation into the United States of Merck's V114 vaccine does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '060 patent under 35 U.S.C. § 271(a), (b), or (c).

94. Pursuant to 28 U.S.C. §§ 2201, *et seq.*, Merck is entitled to a declaratory judgment that V114 does not and will not infringe any valid and enforceable claim of the '060 patent.

PRAYER FOR RELIEF

WHEREFORE, Merck respectfully requests that this Court:

A. Declare that all claims of the ’024 patent are invalid;

B. Declare that all claims of the ’708 patent are invalid;

C. Declare that all claims of the ’060 patent are invalid;

D. Declare that Merck’s V114 does not and will not infringe any valid and enforceable claim of the ’024 patent;

E. Declare that Merck’s V114 does not and will not infringe any valid and enforceable claim of the ’708 patent;

F. Declare the Merck’s V114 does not and will not infringe any valid and enforceable claim of the ’060 patent;

G. Award Merck its costs, disbursements, and other expenses to the fullest extent permitted by law; and

H. Award Merck such other relief as the nature of the case may admit or require, and any such other relief as this Court deems just and proper.

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