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

ADRIANA M. CASTRO, M.D., P.A. on behalf of itself and all others similarly situated, Plaintiff, Vs. SANOFI PASTEUR INC., Defendant.	Civil Action No.: CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff Adriana M. Castro, M.D., P.A. ("Plaintiff") is a professional corporation operating a medical practice with an office at 9220 S.W. 72nd Street, Suite 102, Miami, Florida 33173-3015. Plaintiff brings this class action to challenge an anticompetitive scheme by defendant Sanofi Pasteur Inc. ("Defendant" or "Sanofi") to enhance and maintain Sanofi's monopoly power in the U.S. market for meningococcal vaccines in violation of U.S. antitrust laws. Plaintiff purchased meningococcal vaccines directly from Sanofi or through its fully owned and controlled wholesaling arm VaxServe, Inc. ("VaxServe") during the Class Period (defined below), and brings this case on behalf of itself and a class of similarly situated direct purchasers of meningococcal vaccine, to recover overcharges resulting from the illegal monopolization scheme alleged herein.

I. NATURE OF THE ACTION

1. Sanofi dominates U.S. sales in the markets for multiple pediatric vaccines, including, *e.g.*: (a) DTaP (inoculates against diphtheria, tetanus, and pertussis), (b) Tdap (a stand-alone booster inoculation for diphtheria, tetanus, and pertussis), (c) IPV (inoculates against poliovirus), and Hib (inoculates against haemophilus influenzae type b). Sanofi's brand-name Pentacel combination vaccine (combining the DTaP, IPV, and Hib vaccines) is the number one combination pediatric vaccine in the U.S. Sanofi is the world's largest producer of vaccines and a leading producer of vaccines in the U.S.

2. Sanofi sells its meningococcal pediatric vaccine, which inoculates against bacterial meningitis, under the brand name Menactra. The only other company ever to sell a meningococcal vaccine in the U.S. is Novartis US ("Novartis"). Novartis received FDA approval to sell its Menveo vaccine in February 2010. Despite competition from Menveo—a product which many physicians believe is medically superior to Menactra—Sanofi continues to dominate the meningococcal vaccine market, currently enjoying an overwhelming 93% market share.

3. Sanofi has maintained its dominance in the market for meningococcal vaccines through an anticompetitive and exclusionary scheme involving a web of anticompetitive contracts with multiple physician buying groups ("PBGs") across the U.S., which contracts were designed to impair, and have in fact impaired, Sanofi's vaccine competition in the U.S. These exclusionary contracts have impeded the ability of physicians and hospitals to buy vaccines from Sanofi competitors because these contracts require purchasers to incur substantial price penalties if they buy even small quantities of any pediatric vaccines, including Menveo, from Sanofi's

competitors. For example, one such Sanofi-PBG contract that came into effect in March 2010 provides as follows:

> In order to be linked to our Sanofi Pasteur agreement, you must agree to comply with the following requirements: **Sanofi requires practices linked to this agreement to purchase the full portfolio of their key vaccines – Pentacel, IPOL, DAPTACEL, ActHIB, ADACEL, and Menactra. Practices may not purchase competing products from a different manufacturer and remain compliant.**

4. In fact, physician practice and hospital purchasers must pay Sanofi 15.8% to 34.5% higher prices for *all* of the Sanofi vaccines they buy—including some for which there are no or few available substitutes—if they do not use Sanofi's pediatric vaccines exclusively, or near exclusively. In effect, through its bundled pricing contracts, Sanofi has the power to, and does, raise the costs associated with buying from its competitors—including, notably, raising the effective price of buying Menveo from Novartis.

5. Sanofi's exclusionary scheme also involves Sanofi's efforts to enforce the exclusionary provisions of its PBG contracts in order to punish buyers who defect to purchase even small quantities of vaccines, including notably meningococcal vaccines, from Sanofi's rivals.

6. Sanofi's scheme has made the cost of buying Menveo from Novartis prohibitively expensive to a great deal of physician practices, and has thereby made it impossible, or nearly so, for Novartis and other actual or potential competitors to compete fairly for market share. Sanofi's scheme has thereby excluded and unreasonably impaired Sanofi's actual and potential pediatric vaccine rivals, such as Novartis's Menveo, a vaccine that many physicians prefer and would otherwise provide for their patients.

7. Sanofi's exclusionary contracting scheme has suppressed competition in the meningococcal vaccine market, prevented a more effective meningococcal vaccine from gaining a foothold in the market and from being able to discipline Sanofi's pricing, and enhanced and maintained unlawfully Sanofi's monopoly power in the meningococcal vaccine market. As a result of the conduct challenged herein, instead of lowering its prices in the face of its only real competition in the meningococcal vaccine market ever, Sanofi proceeded to raise its vaccine prices, and thereby caused Plaintiff and other direct purchasers to pay artificially inflated prices for meningococcal vaccines.

II. PARTIES

8. Plaintiff is a professional corporation operating a medical practice at 9220 S.W. 72nd Street, Suite 102, Miami, Florida 33173-3015. During the Class Period defined below, Plaintiff bought Menactra (and other pediatric vaccines) directly from Sanofi and was injured by paying higher prices due to the illegal conduct described herein.

9. Defendant Sanofi Pasteur Inc. is a company organized under the laws of Delaware, having commercial headquarters at 1 Discovery Drive, Swiftwater, Pennsylvania 18370. Defendant Sanofi Pasteur, Inc. sells pediatric vaccines in the U.S. Sanofi Pasteur Inc. is a wholly owned subsidiary of sanofi-aventis Group. sanofi-aventis Group is a holding company organized under the laws of France.

10. VaxServe, Inc. is the fully owned and controlled wholesaling arm of Sanofi Pasteur Inc. and is a company organized under the laws of Delaware having commercial headquarters at 111 North Washington Avenue, Scranton, Pennsylvania 18503. VaxServe, Inc. distributes pediatric vaccines in the U.S.

11. Sanofi Pasteur, Inc. has facilities in at least 13 states, including sales and marketing offices in this District.

III. JURISDICTION, VENUE, AND INTERSTATE COMMERCE

12. Plaintiff brings this action pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover treble damages, costs of suit, and reasonable attorneys' fees for Sanofi's violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a).

13. Venue is proper in this Court pursuant to section 12 of the Clayton Act, 15 U.S.C. § 22, because Sanofi resides in and is an inhabitant of this District or is found or transacts business in this District and because a substantial part of the events giving rise to Plaintiff's claims occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391.

14. The pharmaceutical products at issue in this case are sold in interstate commerce, and the unlawful activities alleged in this Complaint have occurred in, and have had a substantial effect upon, interstate commerce.

IV. BACKGROUND ON THE SALE OF PEDIATRIC VACCINES IN THE U.S.

15. In 2010, global vaccines sales totaled $28 billion. Vaccines are commonly segmented into two target segments: adult and pediatric. The pediatric vaccine segment is slightly larger and accounts for around 52% of U.S. vaccine sales. Pediatric vaccines sales are also growing at a faster rate (11% per year) than adult vaccines (8.2% per year). There are only five pharmaceutical companies that sell pediatric vaccines in the U.S.: Sanofi, GlaxoSmithKline plc ("GlaxoSmithKline" or "GSK"), Merck & Co., Inc. ("Merck"), Pfizer, Inc. ("Pfizer"), and Novartis. Since at least 2010, Sanofi and Merck have reached agreements for extraordinary cooperation between the two companies in the sales of vaccines in the U.S. They have engaged

in joint ventures in both the animal health and vaccine industries. Sanofi and Merck now market and develop their vaccines in Europe together under the name Sanofi Pasteur MSD.

16. The pediatric vaccine marketplace is highly concentrated among Sanofi, GlaxoSmithKline, Merck, and Pfizer. These four firms provide more than 95% of pediatric vaccines in the U.S. Novartis is a new entrant to the pediatric vaccine marketplace as of February 2010.

17. Vaccines fall in a category known as biologics. Other biologics include such medical therapies as blood components, allergenics, somatic cell, gene therapy, and living cells. Biologics are created by biologic processes rather than being chemically synthesized.

18. While the U.S. Food and Drug Administration ("FDA") regulates both pharmaceuticals and biologics, the regulatory scheme for biologics is different than for pharmaceuticals. Although the FDA requires extensive clinical studies for both pharmaceuticals and biologics, generic biologics do not exist and the Abbreviated New Drug Application ("ANDA") process is not available for biologics. The ANDA process allows pharmaceutical manufacturers to demonstrate chemical equivalency of a generic to a previously approved pharmaceutical to obtain FDA approval, instead of duplicating time-consuming and costly clinical studies. The FDA has not developed an abbreviated process for biologics licensure and potential biologics manufacturers ("sponsors") must always complete their own clinical studies.

19. A sponsor who wishes to begin clinical trials with a vaccine must submit an Investigational New Drug application ("IND") to the FDA. The IND describes the vaccine, its method of manufacture, and quality control tests for release. Upon receiving authorization for the IND from the FDA, the sponsor may proceed to pre-licensure vaccine clinical trials. These clinical trials are done in three phases. Phase 1 trials are safety and immunogenicity studies

performed in a small number of closely monitored subjects. Phase 2 trials are dose-ranging studies and may enroll hundreds of subjects. Finally, Phase 3 trials typically enroll thousands of individuals and provide the critical documentation of effectiveness and important additional safety data required for licensing. If at any stage of the process the data raise significant concerns about either safety or effectiveness, the FDA may request additional information or studies or may halt ongoing clinical studies. If all three phases of clinical trials are successful then the sponsor may submit a Biologics License Application ("BLA"). The BLA will be reviewed by a multidisciplinary FDA review team and the FDA will provide a final response letter to the sponsor. The final response letter often includes further clinical trials that the FDA has decided to require. Upon successful completion of the tasks called for in the final response letter, the FDA will license the vaccine. Only after receiving a FDA license is a company permitted to bring a vaccine to market in the U.S. After licensure, the FDA maintains the ability to require further studies and, if appropriate, to pull a vaccine from the market given that potential adverse events cannot necessarily be anticipated until the vaccine is in wide public use.

20. Fixed costs in developing vaccines are high, in part because many vaccine candidates fail in preclinical and early clinical development. Thus, vaccine markets are particularly difficult for new entrants to penetrate.

21. Vaccines work by provoking a specific immune response that fortifies an individual's immune system against an agent. A vaccine contains a killed or weakened part of a virus or bacteria that is responsible for infection. When a person receives a vaccine, the body reacts by making protective substances called antibodies. These antibodies hold a memory record of the virus or bacteria. If a vaccine is properly administered and the inoculated person

later comes into contact with the actual virus or bacteria then the antibodies will prevent infection.

22. Vaccines are made in several different ways. However, all methods of vaccine manufacture share the same general goal: weaken the virus or bacteria in a way that allows the recipient to develop antibodies without developing symptoms of infection. This involves binding a weakened, inactivated, or incomplete part of the virus or bacteria (the "antigen") to some material, often a sugar or protein (the "carrier") for delivery into the human body.

23. A major problem with vaccines is that they can fail to induce the proper immune response and thus fail to immunize an individual against the targeted agent. Another problem is that an individual's immunity can wane over time and often multiple doses of a vaccine are required to maintain immunity. In such instances, booster vaccines may be used sequentially following initial immunization. Booster vaccines are distinct from initial vaccines and are typically different configurations of the initial vaccine intended to strengthen the immune response to a specific agent.

24. Beginning in 1995, a harmonized U.S. pediatric vaccine schedule, approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians has been published and adopted by the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (the "CDC") annually.

25. Currently there are over 20 diseases that can be prevented with vaccines. As of 2011, the pediatric vaccine schedule requires 11 vaccinations that cover 14 diseases for all people under 18 years of age: (1) hepatitis B, (2) diphtheria, pertussis, and tetanus ("DTaP"), (3) diphtheria, pertussis, and tetanus booster ("Tdap") (4) poliovirus ("IPV"), (5) streptococcus

pneumoniae, (6) haemophilus influenzae type b ("Hib"), (7) rotavirus, (8) measles, mumps, and rubella ("MMR"), (9) varicella virus, (10) hepatitis A, and (11) meningococcal disease. In the U.S., pediatric vaccines are sold separately to the public sector and the private sector.

26. In the public sector, the CDC purchases and provides vaccines based on prices negotiated by the U.S. Department of Health and Human Services. This pricing is available only to specified government entities purchasing under defined circumstances and is not offered to the private sector.

27. In the private sector, physicians, physician practices, and hospitals purchase vaccines directly from manufacturers such as Sanofi or from wholesalers, such as Sanofi's wholesaling subsidiary, VaxServe. Most physicians, practices, and hospitals purchase their vaccines pursuant to contracts negotiated by PBGs.

28. Because the CDC vaccine schedule has expanded to cover 20 diseases that all children are supposed to be inoculated against during the first 2 years of life, it is possible that a child could receive as many as 5 separate vaccine injections during a single office visit. For this reason—and because more vaccines against additional diseases are being developed—manufacturers have been developing combination vaccines. With the use of combination vaccines the number of injections can be reduced without reducing the number of diseases against which a child is protected. A combination vaccine consists of two or more separate immunogens (elements that produce an immune response from the body) combined into a single product. Thus, combination vaccines guard against multiple diseases. In addition to reducing the number of injections—and therefore the amount of pain that children experience—combination vaccines have also been shown to improve the timeliness of vaccination coverage, reduce costs associated with stockpiling and administering separate vaccines, reduce costs

associated with extra health care visits that result from delayed vaccinations, and facilitate the integration of new vaccines into the childhood immunization schedule. For these reasons, combination vaccines are typically preferred to stand-alone vaccines.

A. Background on Meningococcal Vaccines

29. In the U.S, between 1,400 and 2,800 cases of meningococcal disease occur each year. Invasive meningococcal disease can be fatal: even with antibiotic treatment, the mortality rate is between 9% and 12%. Up to 20% of the survivors of invasive meningococcal disease have permanent injury, including brain damage, hearing loss, or loss of a limb.

30. Five serogroups—groups of bacteria that contain a common antigen able to generate an immune response—are collectively responsible for nearly all invasive meningococcal disease: groups A, B, C, Y, and W-135. Meningococcal vaccine in the U.S. provides excellent protection against serogroups A, C, Y, and W-135.

31. There are two types of meningococcal vaccines: polysaccharide and conjugate. Polysaccharide and conjugate are different types of vaccine technologies. In a polysaccharide vaccine the antigen is bound to a sugar carrier. In a conjugate vaccine the antigen is bound to a protein carrier. Polysaccharide vaccines were developed in the 1930s and 1940s. Conjugate vaccines were developed in the late 1980s. Conjugate vaccines have several advantaged over polysaccharide vaccines such as reduction in bacterial carriage in the nose and throat, longer duration of immunity, and better immunologic memory. Thus, if both a polysaccharide vaccine and a conjugate vaccine are available, the conjugate vaccine is always preferred.

32. In January 1978, Connaught Laboratories (a predecessor to Sanofi), licensed MCVS4 (“Menomune”), the first polysaccharide meningococcal vaccine in the U.S. However, because Menomune was found to induce a relatively poor immune response in children younger

than two and was not able to elicit long-term immunologic memory, it has never been a widely used vaccine.

33. Between 1978 and 1998, there were major advancements in the development of various conjugate vaccines. In or around 1998, aware of the large potential market, Sanofi, Novartis, and GlaxoSmithKline, respectively, each undertook plans to develop an effective conjugate meningococcal vaccines that could vaccinate against multiple bacterial serogroups.

34. In 1999, SmithKline Beecham (now GlaxoSmithKline) began development of a conjugate meningococcal vaccine by purchasing a license to study a bacterial serogroup B meningococcal vaccine that was developed in Cuba.

35. Between 1994 and 2006, Novartis owned a 48% stake in vaccine manufacturer Chiron Corporation. Chiron Corporation had been developing a conjugate meningococcal vaccine since at least 1999. In 2004, Novartis executives decided to enter the meningococcal vaccine market and thus Novartis acquired Chiron Corporation in 2005.

36. Between 1998 and 2005, Sanofi, Novartis/Chiron, and GlaxoSmithKline raced to be the first to launch a conjugate meningococcal vaccine in the U.S.

37. By 2001, Sanofi had developed a quadrivalent (A, C, Y, W-135) conjugate meningococcal vaccine ("MCV4") and filed an application with the FDA to begin the U.S. vaccine licensure process. In 2003, Sanofi received a complete response letter from the FDA concerning Sanofi's BLA for the MCV4 vaccine. In January 2005, the FDA granted Sanofi a license to sell MCV4 under the name Menactra in the U.S., and Sanofi began selling Menactra in the U.S. immediately thereafter. Menactra was the first MCV4 vaccine that was sold in the U.S.

38. In October 2005, the CDC added meningococcal vaccine to the recommended immunization schedule. It recommended one dose for children and adolescents between 11 and 18—typically at a routine immunization visit at 11 to 12 years of age.

39. In October 2007, the FDA approved Menactra for use in children 2 to 10 years of age.

40. Bolstered by the CDC's decision to add meningococcal vaccine to the recommended immunization schedule, Sanofi's sales of Menactra in the U.S. climbed from under $100 million in 2005 to over $400 million in 2010.

41. In June 2009, Novartis received a complete response letter from the FDA for Novartis's BLA for its MCV4 vaccine. In February 2010, the FDA approved Novartis's MCV4 vaccine for sale in the U.S under the name Menveo, and Novartis began selling Menveo in the U.S. immediately thereafter. Menveo was the second quadrivalent (A, C, Y, W-135) conjugate meningococcal vaccine for use in people from 2 to 55 years of age. Although Menactra and Menveo are similar vaccines that inoculate against the same bacterial meningococcal serogroups, they are conjugated to different protein carriers and contain different quantities of antigens. Data from thousands of young children and adolescents collected during Menveo's Phase 3 clinical trials compared Menactra and Menveo. This data demonstrated that Novartis's Menveo is significantly more effective than Sanofi's Menactra in generating the appropriate meningococcal immune response and protective antibodies in adolescents.

42. In October 2010, the Center for Disease Control and Prevention Advisory Committee on Immunization Practices voted to recommend that all individuals receive a second dose of meningococcal vaccine five years after the initial dose.

43. In September 2011, GlaxoSmithKline received a complete response letter from the FDA in response to its BLA for its meningococcal vaccine Hib-MenCY-TT ("MenHibrix"). As of October 2011, GlaxoSmithKline was still working to obtain FDA approval to sell MenHibrix.

V. RELEVANT MARKETS AND MONOPOLY POWER

A. Relevant Product Markets

44. Insofar as Plaintiff is required to prove monopoly power circumstantially by first defining a relevant product market, five product markets are potentially relevant to Plaintiff's antitrust claims: (1) effective vaccines that inoculate against bacterial meningitis serogroups A, C, Y, and W-135 (the "meningococcal" vaccine market); (2) effective vaccines that inoculate against diphtheria, pertussis, and tetanus, including stand-alone DTaP vaccines and combination vaccines that inoculate against other diseases but include DTaP (the "DTaP" vaccine market); (3) effective stand-alone booster vaccines that inoculate against diphtheria, pertussis, and tetanus (the "Tdap" vaccine market); (4) effective vaccines that inoculate against poliovirus, including stand-alone IPV vaccines and combination vaccines that inoculate against other diseases but include IPV (the "IPV" vaccine market); and (5) effective vaccines that inoculate against haemophilus influenzae type b (the "Hib" vaccine market).

1) Meningococcal Vaccine Market

45. The sale of meningococcal vaccines in the U.S. is a relevant product market.

46. Meningococcal vaccine inoculates against bacterial meningitis serogroups A, C, Y, and W-135. Meningococcal vaccine is a relatively new vaccine that was first sold in the U.S. in 2005.

47. The meningococcal vaccine market contains all FDA approved vaccines that inoculate against bacterial meningitis serogroups A, C, Y, and W-135.

48. The pediatric immunization schedule recommends meningococcal vaccine as a two dose series with the first dose sometime between 11 to 12 years and the second dose at 16 years.

49. Sanofi sells the dominant meningococcal vaccine under the brand name Menactra. Sanofi began selling Menactra in January 2005. On or about February 19, 2010, Novartis introduced Menactra's only U.S. competitor under the brand name Menveo. There are no combination vaccines that include meningococcal vaccine.[1]

50. There are no medical or other reasonably available substitutes for meningococcal vaccines and no other vaccine inoculates against bacterial meningitis serogroups A, C, Y, and W-135.

51. Prior to February 2010, Sanofi had 100% of the relevant market. Subsequent to February 2010, and just after Menveo entered, Sanofi's share dropped but it remained in excess of 80%. After Sanofi redoubled its efforts to enforce its anticompetitive PBG contracts, its share of the meningococcal vaccine market jumped back above 93%, where it stands today.

52. At all relevant times, Sanofi possessed monopoly power—the ability to profitably raise price significantly above competitive levels without losing significant sales—in the meningococcal vaccine market. A small but significant, non-transitory price increase by Sanofi of Menactra would not have caused a significant loss of sales.

[1] Sanofi sells one other meningococcal vaccine under the brand name Menomune. The FDA does not recommend Menomune for pediatric use. However, there are certain rare instances where Menomune is used in patients under age 18. Thus, Menomune has had a consistent but less than 1% share of the meningococcal pediatric vaccine market.

53. Products in the meningococcal vaccine market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the meningococcal vaccine market.

54. Sanofi sold its meningococcal vaccines at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

2) DTaP Vaccine Market

55. The sale of DTaP vaccines in the U.S. is a relevant product market.

56. DTaP vaccines inoculate against three diseases: diphtheria, tetanus, and pertussis. Diptheria is a highly contagious bacterial infection of the upper respiratory tract that can lead to death due to inflammation of the nose and throat. Tetanus is an infection of the nervous system with potentially deadly bacteria. Tetanus vaccine is not effective long-term and the CDC recommends that all adults receives a booster Tetanus shot every 10 years. Pertussis (also known as whooping cough) is a highly contagious bacterial disease that causes uncontrollable violent coughing.

57. The DTaP market contains all FDA approved vaccines that inoculate against diphtheria, pertussis, and tetanus. DTaP itself is a combination vaccine. However, the DTaP combination has become so commonplace that the stand-alone vaccines for diphtheria, pertussis, and tetanus are no longer widely offered and almost every child in the U.S. receives the combination DTaP vaccination.

58. The pediatric immunization schedule recommends DTaP vaccination as a five dose series. The first three doses are given at 2, 4, and 6 months of age. A fourth dose is typically given at between 15 and 18 months. A fifth dose is given at age 4 to 6. This fifth dose is followed by the Tdap dose at 11 to 18 years of age.

59. There are currently five combination vaccines that comprise the U.S. market for DTaP. Sanofi sells the most widely used vaccines in this market under the brand names Daptacel and Pentacel. Pentacel is a combination vaccine that includes DTaP, IPV, and Hib. Daptacel is the DTaP combination vaccine. GlaxoSmithKline sells DTaP vaccines called Infanrix, Pediarix, and Kinrix. Infanrix is the DTaP combination vaccine. Pediarix is a combination vaccine that includes DTaP, IPV, and HepB. Kinrix is a combination vaccine that includes DTaP and IPV but is only FDA approved for the final dose of the DTaP and IPV vaccination series.

60. There are no medical or other reasonably available substitutes for DTaP vaccines and no other vaccines inoculate against diphtheria, tetanus, and pertussis.

61. During the relevant times, Sanofi has had a 66% share of the DTaP vaccine market.

62. At all relevant times, Sanofi possessed monopoly power—the ability to profitably raise price significantly above competitive levels without losing significant sales—in the DTaP market. A small but significant, non-transitory price increase by Sanofi of Daptacel or Pentacel would not have caused a significant loss of sales.

63. Products in the DTaP vaccine market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the DTaP market.

64. Sanofi sold its DTaP vaccines at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

3) Tdap Vaccine Market

65. The sale of Tdap vaccines in the U.S. is a relevant product market.

66. Tdap is a booster vaccine for DTaP. In early 2006, the CDC Advisory Committee on Immunization Practices recommended that a weak formulation of DTaP vaccine referred to as Tdap vaccine be recommended for administration to all adolescents between 11 and 18 years of age. The CDC adopted the recommendation and placed Tdap on the pediatric immunization schedule.

67. The Tdap market contains all FDA approved vaccines that provide booster inoculation against diphtheria, pertussis, and tetanus.

68. The pediatric immunization schedule recommends one dose of Tdap for all children at some point between age 11 and 18.

69. There are only two vaccines that comprise the U.S. market for Tdap. Sanofi sells the most widely used vaccine in this market under the brand name Adacel. Adacel is a stand-alone Tdap vaccine. GlaxoSmithKline sells the other stand-alone Tdap vaccine under the brand name Boostrix.

70. There are no medical or other reasonably available substitutes for Tdap and no other vaccine provides booster inoculation against diphtheria, pertussis, and tetanus. DTaP is not a substitute for Tdap because they contain different concentrations of antigens and the CDC specifically advises against substituting DTaP for Tdap or Tdap for DTaP. Tdap is not included in any combination vaccine.

71. During the relevant times, Sanofi has had a 71% share of the Tdap vaccine market.

72. At all relevant times, Sanofi possessed monopoly power—the ability to profitably raise price significantly above competitive levels without losing significant sales—in the Tdap

market. A small but significant, non-transitory price increase by Sanofi of Adacel would not have caused a significant loss of sales.

73. Products in the Tdap vaccine market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the Tdap market.

74. Sanofi sold its Tdap vaccines at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

4) IPV Vaccine Market

75. The sale of IPV vaccines in the U.S. is a relevant product market.

76. IPV is a vaccine that inoculates against poliovirus. Poliovirus is a viral disease that can affect nerves and can lead to partial or full paralysis.

77. The IPV market contains all FDA approved vaccines that inoculate against poliovirus.

78. The pediatric immunization schedule recommends IPV vaccination as a four dose series given at 2, 4, and 6 to 18 months with a final booster dose at 4 to 6 years.

79. There are currently four vaccines that comprise the U.S. market for IPV. Sanofi sells the most widely used products in this market under the brand names IPOL and Pentacel. IPOL is the only stand-alone vaccine in the IPV market. GlaxoSmithKline sells two combination IPV vaccines under the brand names Pediarix and Kinrix. Kinrix is only FDA approved as the fourth and final dose of an IPV series following Pediarix.

80. There are no medical or other reasonably available substitutes for IPV vaccines and no other vaccine inoculates against poliovirus.

81. During the relevant times, Sanofi has had a 59% share of the IPV vaccine market.

82. At all relevant times, Sanofi possessed monopoly power—the ability to profitably raise price significantly above competitive levels without losing significant sales—in the IPV vaccine market. A small but significant, non-transitory price increase by Sanofi of IPOL or Pentacel would not have caused a significant loss of sales.

83. Products in the IPV vaccine market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the IPV market.

84. Sanofi sold its IPV vaccines at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

5) Hib Vaccine Market

85. The sale of Hib vaccines in the U.S. is a relevant product market.

86. Hib vaccine inoculates against haemophilus influenzae type b. Hib vaccine has been in routine use since 1985.

87. The Hib vaccine market contains all FDA approved vaccines that inoculate against haemophilus influenzae type b.

88. Depending on the brand of vaccine used, the pediatric immunization schedule recommends Hib as a three or four dose series at 2, 4, and 6 months (depending on the brand of vaccine), and a final booster dose at 12 to 15 months.

89. There are currently five vaccines that comprised the U.S. market for Hib. Sanofi sells the most widely used vaccines in this market under the brand names ActHIB and Pentacel. ActHIB is a stand-alone Hib vaccine and Pentacel is the same combination DTaP, IPV, and Hib vaccine that was discussed above. Merck sells two vaccines: PedvaxHIB is a stand-alone Hib vaccine and Comvax is a combination Hib and HepB vaccine. GlaxoSmithKline sells one stand-

alone Hib vaccine called Hiberix that is only FDA approved as the final booster dose (at 12 to 15 months) in the Hib vaccination series.

90. There are no medical or other reasonably available substitutes for Hib vaccines and no other vaccine inoculates against haemophilus influenzae type b.

91. During the relevant times, Sanofi has had a 68% share of the Hib vaccine market. Further, from December 13, 2007 through August 2010, production problems caused Merck to suspend sales of its stand-alone Hib vaccine PedvaxHIB and its combination Hib vaccine Comvax. As previously noted, GlaxoSmithKline's Hiberix is only licensed for the final dose of the Hib series. Thus, during the December 13, 2007 to August 2010 period Sanofi's ActHIB and Pentacel were the only Hib vaccines on the market for the first two to three doses of the Hib series.

92. At all relevant times, Sanofi possessed monopoly power—the ability to profitably raise price significantly above competitive levels without losing significant sales—in the Hib vaccine market. A small but significant, non-transitory price increase by Sanofi of ActHIB or Pentacel would not have caused a significant loss of sales.

93. Products in the Hib vaccine market do not exhibit significant, positive cross-elasticity of demand with respect to price with products that are not in the Hib market.

94. Sanofi sold its Hib vaccines at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

B. Relevant Product Markets - Barriers to Entry

95. In each of the aforementioned relevant markets, barriers to entry—including high fixed costs, high risk of failure in the development process, and difficult regulatory hurdles—render the entry of any new competitor difficult. Vaccine development is risky because most

vaccine candidates fail in preclinical or early clinical development. Human vaccines must meet extremely stringent regulatory and safety requirements set forth by the FDA. Due to these FDA requirements, the vaccine development process may take up to 15 years and substantial sums of money to complete. Indeed, GlaxoSmithKline has been attempting to develop a meningococcal vaccine for over a decade and has yet to win FDA approval. In addition to costs spent directly on development, vaccine manufacturers spend a great deal to construct facilities to manufacture vaccines. Further, there is no abbreviated process by which a vaccine can win FDA approval. Every vaccine must go through the entire FDA licensure process even if it is biologically equivalent to another vaccine. Thus, there are very rarely new vaccines or new competitors within the pediatric vaccine industry.

C. Relevant Geographic Market

96. The relevant geographic market for all of the vaccines at issue in this case is the U.S. (including all U.S. territories and commonwealths). Pediatric vaccines manufacturers market and distribute their vaccines throughout the U.S. The anticompetitive contracts at issue in this case affect only U.S. sales of the relevant products. Pediatric vaccines require FDA licensing before they can be sold in the U.S.

VI. SANOFI HAS WILLFULLY MAINTAINED AND EXPANDED ITS MONOPOLY POWER IN THE MENINGOCOCCAL VACCINE MARKET THROUGH THE USE OF AN ANTICOMPETITIVE EXCLUSIONARY CONTRACTING SCHEME

97. As discussed above, the U.S. pediatric vaccine marketplace is characterized by high fixed costs for entry, risk of failure during the vaccine development process, and significant regulatory hurdles.

98. Compared to other pharmaceutical products, incumbent vaccines are sheltered from competitive entry because access to proprietary cell lines and virus strains are more

valuable than patent protection. Generic vaccines do not exist and the Abbreviated New Drug Application ("ANDA") process—used for gaining approval of most generic prescription drugs in the U.S. — is not available for biologics. This means that would-be vaccine sellers in the U.S. must duplicate the time-consuming and costly clinical studies that the FDA requires for vaccine licensure.

99. Over the last few decades, the number of vaccine manufacturers in the U.S. has decreased significantly. In 1967, 26 different companies held vaccine licenses in the U.S. while only 12 companies held such licenses in 2002.

100. The below chart summarizes the pediatric vaccine products manufactured by Sanofi and Sanofi's competitors in 2011:

	Sanofi	**GSK**	**Merck**	**Novartis**	**Pfizer**[6]
Hepatitis B		Engerix B Twinrix* Pediarix*	Recombivax Comvax*[3]		
DTaP	Daptacel Pentacel*	Infanrix Kinrix* Pediarix*			
Tdap (DTaP booster)	Adacel	Boostrix			
Polio (IPV)	IPOL Pentacel*	Kinrix* Pediarix*			
Streptococcus			Pneumovax[4]		Prevnar
Hib	ActHIB Pentacel*	Hiberix[1]	PedvaxHIB[3] Comvax*[3]		
Rotavirus		Rotarix	RotaTeq		
MMR			MMRII		
Varicella			Varivax		
Hepatitis A		Havrix Twinrix*	Vaqta		
Meningitis (MCV4)	Menactra Menomune[2]			Menveo[5]	

*Combination vaccine.

[1]Limited use. Hib is administered as a three or four dose series. GlaxoSmithKline's Hiberix was licensed in August 2009 but is only licensed for the final dose of the three or four dose Hib series.

[2]Not widely used because Menactra is more effective.

[3]Subject of major Merck recall in 2007. Merck had limited supplies available for sale from 2007 through 2010.
[4]Licensed in 2011.
[5]Licensed in February 2010.
[6]Prevnar was originally developed and manufactured by Wyeth. Pfizer acquired Wyeth in 2009.

101. Physician and hospital purchasers need to buy all or nearly all vaccines on the pediatric vaccine schedule. The majority of physician practice and hospital purchasers do this by contracting with Sanofi and Merck.[2] A minority of physician practice and hospital purchasers use GlaxoSmithKline as their primary vaccine supplier. Purchasers are increasingly unable to use GlaxoSmithKline as a primary vaccine supplier because: (1) there are exclusive contracts between PBGs and Sanofi/Merck; (2) Sanofi and Merck have become increasingly cooperative over the last decade; (3) GlaxoSmithKline does not have a meningococcal vaccine on the market; and (4) GlaxoSmithKline's sole Hib vaccine is only FDA approved for the final dose in the three to four dose Hib series.

A. Sanofi's Exclusionary Contracting Schemes

102. Sanofi has entered into exclusionary contracts with a majority of PBGs, covering the vast majority of physician and hospital vaccine private sector purchasers, which contracts penalize these purchasers for buying vaccines from rivals.

103. PBGs are typically privately held, for-profit entities, with membership consisting of thousands of family practices, pediatricians, and other independent medical practices. The vast majority of family practices, pediatricians, and other independent medical practices in the U.S. are members of a PBG. PBGs function like Group Purchasing Organizations ("GPOs"), which tend to serve groups of hospitals and clinics. PBGs and GPOs, despite their names, do not

[2] Up until 2011 when Merck's Pneumovax streptococcus vaccine received FDA approval, Sanofi/Merck contracts made a specific exception that allowed purchasers to buy Prevnar from Pfizer/Wyeth.

actually buy anything.[3] Rather, PBGs (and GPOs) perform various services on behalf of their members, including coordinating and aggregating member purchases of vaccines and other healthcare supplies through group purchasing contracts with major vaccine manufacturers and medical supply distributors. Most or all of PBGs' compensation comes in the form of rebates and administrative fees paid by vendors (based on PBG members' aggregate expenditures). PBGs typically require that participating practices agree to contractual terms to be eligible to purchase vaccines and other products pursuant to the PBG group purchasing contracts

104. Under Sanofi's exclusionary contracts with PBGs buyers face a steep price penalty ranging from 15.8% to 34.5% of the costs of all vaccine purchases from Sanofi in a given period if they obtain vaccines from Sanofi competitors such as Novartis. Specifically, Sanofi has entered into a web of contracts with PBGs that impose stiff price penalties on the entire range of a buyer's Sanofi pediatric vaccine purchases, including DTaP, Tdap, IPV, Hib, and meningococcal vaccines, if that buyer satisfies even some of its purchase requirements for any one of these vaccines with products from Sanofi's rivals.

105. Sanofi utilized this exclusionary contracting scheme in direct response to the competitive threats. In or before 2005, Sanofi Pasteur began imposing the following bundled pricing provisions on physician and hospital purchasers through PBGs: if a buying group member failed to purchase 90% or more of its pediatric vaccine requirements from Sanofi, it would be forced to pay prices 25-35% higher on *all* of the vaccines in Sanofi's pediatric vaccine bundle, including Sanofi's Hib vaccines Pentacel and ActHIB, for which there are no medically adequate substitutes available. Thus, if a physician practice or hospital bought more than 10% of its requirements for meningococcal vaccines from Novartis (after Novartis entered in February

[3] Sanofi may also have entered into exclusionary contracts for the sale of pediatric vaccines with GPOs.

2010) then it would pay a stiff penalty on all of the vaccines in the Sanofi bundle. For example, a pediatric practice that buys $10,000 per month in pediatric vaccines from Sanofi risks having its costs rise for all Sanofi vaccines it purchases by over $3,400 per month simply for buying $1,000 of Menveo from Novartis. If any member of a physician practice fails to comply with the exclusivity requirements, then the entire practice pays penalty prices on all Sanofi vaccines in the bundle. In effect, through the bundled pricing scheme, Sanofi is able to raise the price for purchasers of buying its competitor's products.

106. In or before 2010, in part as a response to Novartis's release of Menveo in February 2010, Sanofi intentionally altered many of its bundled pricing contracts by increasing the pediatric vaccine purchasing requirements to 100% for all or most of Sanofi's vaccines. Under the new Sanofi-PBG contracts, if a purchaser buys *any* vaccines from a Sanofi competitor then that purchaser faces a stiff penalty on all of the vaccines in the Sanofi bundle.

107. Sanofi entered exclusionary contracts like those described above with PBGs across the U.S., including Atlantic Health Partners LLC, Kelson Physician Partners, Inc., Main Street Vaccines, National Physician Care, Inc., PedsPal/Cooks Children, Unified Physicians Society, and Physicians' Alliance of America. The Sanofi-PBG contracts impose these anticompetitive and exclusionary bundling terms for Sanofi vaccines on physician, practice, health clinic, and hospital purchasers. Under the terms of Sanofi's contracts with PBGs, the PBGs agreed to require and enforce the requirement that all participating practices agree to buy 90% or more of their requirements for each of the following vaccines from Sanofi: DTaP, Tdap, IPV, Hib, and meningococcal vaccine.

108. As part of its anticompetitive scheme, Sanofi has actively worked with PBGs to identify and punish non-compliant physician and hospital purchasers. Each year, physician

practice and hospital purchasers are required to demonstrate compliance with Sanofi's purchase level requirements. To do so, the physician practice or hospital purchaser must provide all of its vaccine purchasing records to the PBG for auditing. If a physician practice or hospital purchaser is non-compliant then it must pay substantial penalties on all Sanofi vaccines and/or be removed from the contract entirely. Once removed from the PBG contract, the physician practice or hospital would be be forced to pay Sanofi's penalty prices on all Sanofi vaccines, including Sanofi's Hib vaccines Pentacel and ActHIB for which there are no reasonably adequate medical substitutes.

109. The Physicians' Alliance of America is one of the largest PBGs in the U.S. It has more than 27,000 physician members from all 50 states. Sanofi has entered into an exclusionary bundling contract with the Physicians' Alliance. For example, a March 8, 2010 Sanofi-Physicians' Alliance contract provides as follows:

> In order to be linked to our Sanofi Pasteur agreement, you must agree to comply with the following requirements: **Sanofi requires practices linked to this agreement to purchase the full portfolio of their key vaccines – Pentacel, IPOL, DAPTACEL, ActHIB, ADACEL, and Menactra. Practices may not purchase competing products from a different manufacturer and remain compliant.**

110. The Unified Physicians Society ("UPS") is a for-profit PBG with several thousand physician members (mostly pediatricians). Sanofi and UPS have entered into an exclusionary bundling contract containing a similar provision to the Sanofi-Physicians' Alliance agreement:

> This Commitment Form represents our practice's intent to fully utilize the Unified Physicians Society-Sanofi Pasteur Immunization agreement. We will purchase PENTACEL® (DTaP-HIB-IPV), DAPTACEL® (DTaP), IPOL® (IPV), ActHIB® (Hib), Adacel® (Tdap) and Menactra® (MCV4) exclusively for the complete immunization series (5 DTaP, 4 IPV, 4 Hib, meningococcal and

> Tdap boosters). We understand that failure to comply with this utilization requirement will result in our practice being removed from the entire Immunization Contract Benefit.

111. The FAQs section of the UPS website demonstrates that Sanofi is actively involved in monitoring purchases made through the PBGs. In response to a question about why UPS members must use Sanofi and Merck vaccines exclusively the FAQ provides: "Our contract purchases are monitored by the manufacturers and our discounts/terms are based on members adhering to these guidelines."

112. Main Street Vaccines is a for-profit PBG with around 7,000 physician members. A November 14, 2011 letter from Main Street Vaccines explains that the Sanofi-Main Street Vaccines contract does not set the purchasing requirement below 100% so that purchasers can buy competing vaccines:

> Our benchmark requirements are set below 100% to allow for year to year variation in practice circumstances or vaccine use. They are not there to provide "wiggle room" for the use of competing vaccines. If you succumb to a sales pitch and buy Menveo® or Boostrix® you will not get the 1% bonus and may put your 2.5% annual rebate at risk.

113. The following chart summarizes many of the PBGs that have exclusionary bundling contracts with Sanofi that contain provisions similar to those set out above:

Name	**Description**	**Membership**
Atlantic Health Partners	PBG specializing in vaccines	"Leading physician vaccine buying group with Family Physicians across the country"
Child Health Corporation of America	Hospital-owned PBG	Hospitals representing more than 20,000 physicians
Cook Children's Physician Network	Non-profit healthcare system with vaccine purchasing program	~300 physicians
Cumberland Pediatric Foundation	Non-profit foundation with vaccine purchasing program	Unknown
Kelson Physician Partners, Inc.	Pediatric healthcare services provider with vaccine	4,200 physicians in 38 states

	purchasing program	
Main Street Vaccines	Nationwide physician PBG	More than 7,000 physicians
National Physician Care, Inc.	PBG representing private practice physicians, non-governmental health clinics, corporate employee health clinics, and travel clinics	5,000 medical practices and 20,000 practitioners
Physicians' Alliance of America	Non-profit physician-owned PGB	More than 27,000 physicians
Primary Care Alliance	For-profit PBG	Unknown
Unified Physicians Society	For-profit PBG	Thousands (mostly pediatricians)

114. On information and belief, Sanofi has bundled-pricing contracts with exclusionary provisions with PBGs covering the majority of physician and hospital purchasers of pediatric vaccines in the U.S. Under the terms of these contracts with PBGs, physician practice and hospital purchasers must purchase 90% or more of each vaccine in the bundle from Sanofi to avoid severe price penalties on all Sanofi vaccines.

115. These exclusionary contracts prevent the physician practice or hospital purchaser from freely purchasing meningococcal vaccine from Novartis or any would-be rival. Failure to comply with Sanofi's restrictions results in the purchaser being removed from the contract and being subjected to 15.8% to 34.5% price penalties on all of its purchases of Sanofi pediatric vaccines, including Sanofi's Hib vaccines ActHIB and Pentacel for which there are no reasonably adequate medical substitutes.

B. Sanofi and Merck

116. Sanofi has had a cooperative relationship with Merck relating to the sale of pediatric vaccines over the last decade. Sanofi and Merck market their vaccines together in Europe through their joint venture Sanofi Pasteur MSD. Sanofi and Merck have also undertaken cooperative ventures in selling animal health products in the U.S. Merck manufactures pediatric vaccines for streptococcus, Hib, rotavirus, MMR, varicella virus, and hepatitis A. Sanofi does

not produce vaccines for rotavirus, MMR, varicella virus, and hepatitis A. Thus, Merck's pediatric vaccine offerings complement Sanofi's pediatric vaccine offerings and together Merck and Sanofi manufacture pediatric vaccines that cover almost the entire pediatric immunization schedule.

117. Sanofi and Merck's cooperation has aided Sanofi's anticompetitive scheme of using its exclusionary contracts and bundled pricing to impede the sales and growth of two pediatric vaccine rivals: GlaxoSmithKline (which makes several, but not all key pediatric vaccines and notably lacks a meningococcal vaccine and a Hib vaccine that is approved for the entire Hib series) and Novartis (which makes only one vaccine: Menveo in the market for meningococcal vaccines).

118. Communications between PBGs and their members reveal substantial cooperation between Sanofi and Merck with regard to childhood vaccine sales in the U.S. For example, the Primary Care Alliance ("PCA") PBG told its members in a March 26, 2010 letter: "We know as a PCA member you are committed to support the contracts PCA has signed with Sanofi Pasteur and Merck. We appreciate your loyalty."

119. The same acknowledgement of the relationship between Sanofi and Merck is found in a Cumberland Pediatric Foundation Vaccine Contract PBG letter to its members on April 26, 2010:

> Many of our members have reported GSK and Novartis representatives telling practices that they can "have the best of both worlds" and order just one box of vaccines from them which will give them discounts on their vaccines. Practices have also been told that it does not matter from a compliance standpoint if they order GSK and Novartis products while on a Sanofi contract. **This is not the case.** (emphasis added).

And further,

> Members have reported to us that GSK and Novartis representatives have stated the purchase of these products would not jeopardize their Sanofi and/or Merck group pricing. **This is NOT correct! Both of our agreements, (Sanofi Pasteur and Merck), contain pricing discounts earned by the collective membership maintaining purchases of the core product portfolios. Deviation from this will put the entire contract at risk and have a negative impact on our ability to offer you (our members) the best available upfront discounts on vaccines.**

And further,

> **Please know that by your participation in the Merck/Sanofi vaccine contracts, you cannot also participate in a GSK or Novartis contract. All vaccines with the exception of Prevnar can be purchased through your Merck or Sanofi contract.**[4]

120. The above language from the Primary Care Alliance and Cumberland Pediatric Foundation letters demonstrates that physician practice and hospital purchasers, as well as PBGs, are aware of the cooperation between Sanofi and Merck. Almost all PBGs that have an exclusive contract with Sanofi also have contracts with Merck.

121. The above letters from major PBGs also demonstrate that GlaxoSmithKline and Novartis have been attempting to market to physician practice and hospital purchasers that currently have Sanofi/Merck contracts. Sanofi has responded to efforts of its pediatric vaccine rivals to gain market share by both engaging in the exclusionary contracts described herein, and pressuring PBGs to enforce those contracts with PBG members. PBGs have stepped in to enforce the terms of Sanofi's (and Merck's) exclusionary contracts to ensure that GlaxoSmithKline and Novartis are unable to take sales from Sanofi.

122. As a result of Sanofi's exclusive contracting scheme, the vast majority of physician practice and hospital purchasers are foreclosed from fulfilling material amounts of

[4] In 2011, the FDA licensed Merck's streptococcus vaccine Pneumovax. Thus, all pediatric vaccines can be purchased via a Sanofi/Merck contract and Prevnar no longer needs to be purchased off contract.

pediatric vaccines from Sanofi's rivals (other than Merck) because such purchases would cause the assessment of punitive price penalties on all Sanofi vaccines purchased, including those with no adequate substitutes. Paying Sanofi's penalty prices would put physician and hospital purchasers at a severe disadvantage because they, in turn, could not offer pediatric vaccines at commercially viable prices.

C. Sanofi's Exclusionary Contracting Scheme Has Foreclosed a Substantial Amount of Competition in the Meningococcal Vaccine Market

123. Meningococcal vaccine was added to the recommended immunization schedule in 2005. Meningococcal vaccine is administered as two doses to patients between the ages of 11 to 18. Since vaccines are sold and priced by the dose and not the series, all purchasers must buy two doses of Menactra to fulfill the inoculation needs of a single patient.

124. Sanofi's Menactra is a stand-alone vaccine. Menactra is administered as two doses between 11 and 18 years of age. The FDA approved Menactra in 2005.

125. From January 2005 to February 2010, Sanofi was the sole manufacturer of meningococcal vaccine in the U.S. Sanofi's Menactra had $400 million in U.S. revenues in 2010.

126. The only other company that manufactures meningococcal vaccine in the U.S. is Novartis. In February 2010, Novartis received FDA approval to sell its meningitis vaccine, Menveo, in the U.S. and Novartis began selling it immediately thereafter. Menveo is Novartis's only FDA approved vaccine. Menveo is a stand-alone meningococcal vaccine. Menveo is administered as two doses between 11 and 18 years of age. As discussed above, several clinical studies have concluded that Menveo is a more effective vaccine than Menactra.

127. The exclusionary contracts between Sanofi and PBGs have had the purpose and effect of unfairly impeding Novartis's ability to compete fairly in the meningococcal vaccine

market. Sanofi's exclusive contracts with PBGs require that purchasers buy 90% or more of their DTaP, Tdap, IPV, Hib, and meningococcal vaccine requirements from Sanofi to avoid price penalties on Menactra. Sanofi is aware that this bundling blocks Novartis's ability to compete fairly because, through the bundled pricing, a purchaser who buys Novartis's Menveo instead of Menactra for some of its meningococcal vaccine requirements not only pays a steep price penalty on all of the Menactra that that purchaser buys, but also pays a penalty price to Sanofi on multiple, unrelated, vaccines in unrelated markets—including on vaccines such as DTaP, Tdap, IPV, and Hib. Since Novartis does not produce any other pediatric vaccines besides its meningococcal vaccine, and because physician practices do not tend to buy other medicines that Novartis sells (patients obtain prescription drugs from pharmacies), there is no way that Novartis can compensate a physician practice to make up for Sanofi's price penalties on these other products.

128. As a result of Sanofi's exclusionary contracting scheme, the aggregate penalty that a purchaser pays for buying Menveo is so large that if that purchaser subtracts that penalty form the price of Menactra, the resulting price would be below Sanofi's average variable costs of making Menactra. Accordingly, a hypothetical equally efficient rival with an equivalent meningococcal vaccine would have to sell below its costs (and potentially pay the buyer for fulfilling its vaccine requirements with it) in order to compete on an equal basis with Sanofi. This is because the hypothetical equally efficient competitor to Sanofi would need to compensate the buyer for all the penalties that the buyer would incur (on multiple Sanofi pediatric vaccines) for breaking Sanofi's bundle and buying that rival's meningococcal vaccine.

129. Menactra's market share was close to 100% prior to Menveo's market entry,[5] but that dropped to 81% when Novartis's Menveo was first introduced in February 2010. However, Sanofi reacted by increasing the restrictiveness of its exclusionary contracts, and by more aggressively enforcing the restrictive provisions. Many of Sanofi's contracts had previously required that purchasers buy 90% or more of their pediatric vaccine requirements from each of Sanofi's lines of DTaP, Tdap, IPV, Hib, and meningococcal vaccine. As Menveo gained market share in the first half of 2010, Sanofi raised the requirement from 90% to 100% on some PBG contracts. As a result of Sanofi's conduct and more aggressive enforcement of their terms, Menactra's market share climbed back above 93% by 2011.

130. The below chart summarizes Sanofi's list prices to the private sector for Menactra:

Menactra CDC List Prices 2009 to 2011

Year	2009	2010	2011
Price	$98.52	$103.41	$106.49

131. The expanded market share and monopoly power that Sanofi has achieved in the meningococcal vaccine market by way of its exclusionary contracts with PBGs has allowed Sanofi to raise the price of Menactra despite Menveo coming on the market in February 2010. Since Menveo came on the market, Sanofi has increased the list price of Menactra by 8.1%.

132. As a result of Sanofi's exclusionary contracting scheme, physician practice and hospital purchasers were impeded from purchasing Novartis's Menveo vaccine despite the fact that clinical trials have found that Menveo is more effective than Menactra in triggering the proper immune response in children. As one PBG reminded its members in 2010: "As most of

[5] Sanofi's market share of the meningococcal vaccine market was 100%. Menactra's market share was greater than 99%. Sanofi's other meningococcal vaccine Menomune (that is not FDA recommended for pediatric use) had a market share of less than 1%.

you know, the agreement PCA [the PBG] has with Sanofi Pasteur requires our members to exclusively use their meningococcal vaccine, Menactra."

133. As explained above, in light of the penalties Sanofi imposes on purchasers who violate its contracts and buy vaccines from rivals, Novartis would have to sell its pediatric vaccines below cost or even pay customers to use Menveo. Given that the vast majority of physicians and hospitals across the country seeking to buy vaccines are subjected to Sanofi's exclusionary contracts, it impossible for Novartis to compete effectively with Sanofi's Menactra.

134. Sanofi's exclusionary contracting scheme has substantially foreclosed a superior vaccine from the meningococcal vaccine market and enabled Sanofi to increase its market share in the meningococcal vaccine market while simultaneously raising the price of Menactra. Thus, Plaintiff and other direct purchasers have paid overcharges on meningococcal vaccines since at least February 2010 due to Sanofi's anticompetitive scheme.

VII. SANOFI'S EXCLUSIONARY CONTRACTS ARTIFICALLY INFLATED SANOFI'S MARKET SHARE AND MONOPOLY POWER IN THE MENINGOCOCCAL VACCINE MARKET AND LED TO ARTIFICIALLY INFLATED MENACTRA PRICES

135. Sanofi's exclusionary contracts shield large segments of the vaccine marketplace from competition, thereby stifling competition on the merits as well as the development of new and potentially more effective vaccines. In the case of meningococcal vaccines, Sanofi's conduct has excluded lower-priced and/or superior quality meningococcal vaccines such as Novartis's Menveo. Sanofi has used exclusionary bundling contracts to leverage its monopoly power and dominant market shares in multiple relevant vaccine markets, and its broad product line, to preserve and extend its monopoly power in the meningococcal vaccine market.

136. Had Sanofi not used its anticompetitive contracting scheme to foreclose and stifle Novartis from competing in the meningococcal vaccine market, then Novartis would have achieved much greater sales than it actually did, and it would have posed a far greater competitive threat to Sanofi.

137. The presence of unfettered competition from Novartis and/or other actual or potential competitors would have forced Sanofi to lower the prices of Menactra in order to remain competitive and/or to counter a perceived risk of additional entry. Sanofi would have been forced to lower its meningococcal vaccine prices, including prices paid by purchasers subject to PBG contracts and prices paid by non-contract buyers. Moreover, because price-cutting would have been an effective strategy to compete with Sanofi absent the exclusionary contracting scheme, Plaintiff and other members of the proposed class would have been able to purchase Novartis's vaccine at lower prices as well.

138. There is no valid procompetitive business justification for Sanofi's exclusionary contracts. Sanofi did not use the contracts to achieve economies of scale or other efficiencies.

139. The effect of Sanofi's exclusionary bundle and anticompetitive contracting scheme was that Plaintiff and members of the proposed Class have paid artificially inflated prices for meningococcal vaccines from at least February 2010 through the present. Additionally, Sanofi's exclusionary contracts improperly interfere with the physician-patient relationship by forcing doctors to buy vaccines that may not be the best alternatives for their patients.

CLASS ACTION ALLEGATIONS

140. Plaintiff brings this action on behalf of itself and all others similarly situated pursuant to Rule 23 of the Federal Rules of Civil Procedure as representative of a class (the "Class") defined as follows:

> All persons or entities in the United States and its territories that purchased Menactra directly from Sanofi or any of its divisions, subsidiaries, predecessors, or affiliates, such as VaxServe, Inc. during the period from February 2010 through such time as the effects of Sanofi's illegal conduct have ceased, and excluding all governmental entities, Sanofi, and Sanofi's divisions, subsidiaries, predecessors, and affiliates.

141. On information and belief, hundreds or thousands of entities in the U.S. have purchased Menactra directly from Sanofi. Thus, the Class is so numerous that joinder is impracticable.

142. Plaintiff's claims are typical of those of the Class.

143. Plaintiff and all members of the Class were injured in the form of overcharges by the same conduct of the Defendant.

144. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are not antagonistic to the Class.

145. Plaintiff is represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

146. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members because Sanofi has acted and refused to act on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Sanofi's exclusionary and anticompetitive conduct in monopolizing and attempting to monopolize the meningococcal vaccine market, as more fully alleged herein.

147. Questions of law and fact common to the Class include:

a. whether Sanofi intentionally and unlawfully impaired or impeded competition in the meningococcal vaccine market;

b. whether Sanofi maintained or enhanced monopoly power in the meningococcal vaccine market;

c. whether Sanofi engaged in anticompetitive conduct in order to unlawfully disadvantage its competitors and maintain monopoly power in the meningococcal vaccine market;

d. whether Sanofi had and has monopoly power with respect to DTaP, Tdap, IPV, Hib, and meningococcal vaccines;

e. whether Sanofi had procompetitive reasons for its conduct;

f. the effects of Sanofi's anticompetitive conduct on meningococcal vaccine prices;

g. whether Plaintiff and other members of the Class have been overcharged and thus damaged by paying artificially inflated prices for meningococcal vaccines as a result of Sanofi's unlawful behavior; and

h. the proper measure of damages.

148. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims

that might not be practicable for them to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

149. Plaintiff knows of no difficulty to be encountered in the maintenance of this action as a class action.

FIRST CAUSE OF ACTION
Monopolization
of the Meningococcal Vaccine Market (15 U.S.C. § 2)

150. Plaintiff incorporates by reference the above allegations.

151. At all relevant times, Sanofi has had monopoly power in the DTaP, Tdap, IPV, Hib, and meningococcal vaccine markets.

152. Sanofi has willfully maintained its monopoly power in the meningococcal vaccine market through exclusionary and anticompetitive means. As described in more detail above, Sanofi leveraged its monopoly power in a broad array of vaccine markets by imposing contractual terms on purchasers of its vaccines that severely penalized customers for buying more than a modest amount of vaccines from rivals. Since at least February 2010, Sanofi's exclusionary contracts have unfairly impaired the ability of rivals like Novartis to compete for market share and thereby preserved Sanofi's dominance and monopoly power in the market for meningococcal vaccines. Because Menveo is Novartis's sole pediatric vaccine offering, and Sanofi's bundle links the ability of customers to access non-penalty prices on all of Sanofi's vaccine offerings to customers' purchasing Menactra from Sanofi, there is no price at which a rival, even one as efficient as or more efficient than Sanofi, could effectively compete in the meningococcal vaccines market.

153. By engaging in this conduct and imposing bundled pricing on purchasers, Sanofi has gained an artificial and unlawful competitive advantage from its monopoly power and broad list of product offerings, instead of its lower price or superior quality, and unfairly impeded and impaired competition in the meningococcal vaccine market. The purpose and effect of Sanofi's conduct has been to suppress rather than promote competition on the merits.

154. By suppressing competition and maintaining monopoly power, Sanofi was able to artificially inflate the price of Menactra above levels that would have been obtained in a world in which Sanofi did not engage in the anticompetitive conduct alleged herein. Instead of lowering its price to meet a new rival, Sanofi's exclusionary bundle allowed it to raise its price. Moreover, because Sanofi's conduct removed price cutting as an effective competitive response for Novartis, Menveo's price was higher than it otherwise would have been as well. Accordingly, the challenged conduct caused Plaintiff and members of the proposed Class to pay artificially inflated prices for meningococcal vaccines sold into the private market.

155. There is no procompetitive justification for Sanofi's conduct.

156. Plaintiff has been injured in its businesses and property by reason of Sanofi's unlawful monopolization. Plaintiff's injuries consist of paying higher prices to purchase the relevant products than it would have paid absent Sanofi's conduct. Plaintiff's injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Sanofi's conduct unlawful.

SECOND CAUSE OF ACTION

Anti-Competitive Agreements in Unreasonable Restraint of Trade (15 U.S.C. § 1)

157. Plaintiff incorporates by reference the above allegations.

158. As set forth above, Sanofi has used the pricing of vaccines has monopoly power, including DTaP, Tdap, IPV, Hib, and meningococcal vaccines, to preserve and extend Sanofi's monopoly power in the meningococcal vaccine market. Sanofi entered into agreements with PBGs to enforce its exclusionary bundled vaccine pricing scheme. These agreements included written exclusionary agreements in unreasonable restraint of trade, which included various exclusionary contractual terms.

159. As alleged above, there was no legitimate business justification for these agreements and these agreements: (a) substantially foreclosed and excluded competition from meningococcal vaccine manufacturers; and (b) resulted in Sanofi's willful maintenance and unlawful exercise of monopoly power in the meningococcal vaccine market.

160. At all relevant times, Sanofi's exclusionary agreements assisted Sanofi in: (a) effectively excluding less expensive, superior competitive products from the meningococcal vaccine market; (b) maintaining Sanofi's dominant market share and monopoly power in the meningococcal vaccine market; (c) maintaining prices at artificially high levels for Menactra; and (d) otherwise reaping the benefits of its illegal monopoly power.

161. There is no procompetitive justification for Sanofi's conduct.

162. Plaintiff has been injured in its businesses and property by reason of the alleged collusion and conspiracy, which facilitated, enabled, assisted, and furthered Sanofi's substantial foreclosure and exclusion of competition and monopolization of the meningococcal vaccine market. Plaintiff's injuries consist of paying higher prices to purchase the relevant products than

they would have paid absent Sanofi's unlawful conduct. Plaintiff's injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Sanofi's conduct unlawful.

PETITION FOR RELIEF

WHEREFORE, Plaintiff petitions that:

a. The Court determine that this action may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23, that Plaintiff be appointed class representative, and that Plaintiff's counsel be appointed as counsel for the Class;

b. The conduct alleged herein be declared, adjudged, and/or decreed to be unlawful under Section 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2.

c. Plaintiff and the Class recover their overcharge damages, trebled, and the costs of the suit, including reasonable attorneys' fees as provided by law; and

d. Plaintiff and the Class be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

JURY TRIAL DEMANDED

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of all of the claims asserted in this Complaint so triable.

Dated: December 9, 2011

s/ Peter S. Pearlman
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