



development of Arexvy, GSK has patented its innovative RSV vaccine technology, including the GSK Patents. GSK anticipates that Arexvy will be available to patients no later than this fall.

4. Following approval of GSK's Arexvy, the FDA also approved Pfizer's RSV vaccine for adults 60 years of age and older under the trade name ABRYSVO™ ("Abrysvo"). Upon information and belief, Pfizer began the project that led to Abrysvo no earlier than 2013, at least seven years after GSK started its RSV program. On May 31, 2023, Pfizer announced that it "anticipates supply availability in Q3 2023 ahead of the anticipated RSV season this fall."<sup>1</sup> As of July 19, 2023, Abrysvo had been administered to at least one patient in California.<sup>2</sup>

5. Upon information and belief, Pfizer's manufacture, use, offer for sale, sale, and/or importation of Abrysvo in the United States infringes one or more claims of the GSK Patents.

### **PARTIES**

6. Plaintiff GSK Biologicals is a corporation organized and existing under the laws of Belgium with its principal place of business at Avenue Fleming 20, 1300 Wavre, Belgium. GSK Biologicals is the human vaccine research, development, and commercialization arm of GSK plc. GSK Biologicals develops and improves vaccines to cover a range of global diseases, including shingles, hepatitis, influenza, malaria, and tuberculosis. GSK Biologicals manufactures and distributes Arexvy.

7. GSK Biologicals is the current owner by assignment of numerous United States patents related to RSV vaccine technology, including the GSK Patents asserted in this action.

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<sup>1</sup> Press Release, Pfizer, U.S. FDA Approves ABRYSVO™, Pfizer's Vaccine for the Prevention of Respiratory Syncytial Virus (RSV) in Older Adults (May 31, 2023), *available at* <https://www.pfizer.com/news/press-release/press-release-detail/us-fda-approves-abrysvo™-pfizers-vaccine-prevention>.

<sup>2</sup> See Press Release, GoHealth Urgent Care, RSV Vaccine Administered at Dignity Health-GoHealth Urgent Care (July 19, 2023), *available at* <https://www.gohealthuc.com/news/gohealth-urgent-care-dignity-health-rsv-vaccine>.

8. Plaintiff GSK LLC is a limited liability corporation organized and existing under the laws of Delaware, with its principal place of business at 2929 Walnut St., Suite 1700, Philadelphia, PA 19104. GSK LLC is a global, research-based pharmaceutical company with an industry-leading vaccine portfolio that protects millions of people from infectious diseases each year.

9. GSK Biologicals has designated GSK LLC as the exclusive distributor of Arexvy in the United States.

10. Defendant Pfizer is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 235 East 42nd Street, New York, New York, 10017.

### **JURISDICTION AND VENUE**

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

12. This Court has personal jurisdiction over Pfizer because it is a Delaware corporation.

13. Furthermore, upon information and belief, Pfizer has purposely availed itself of the rights and benefits of the laws of Delaware by engaging in persistent, systematic, and continuous contacts with Delaware. Among other things, Pfizer is in the business of marketing pharmaceutical products, which it distributes and sells throughout the United States, including in Delaware. Upon information and belief, Pfizer's Abrysvo is or will be available in Delaware ahead of the RSV season this fall.

14. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Pfizer is a Delaware corporation.

### **BACKGROUND**

15. This dispute involves Pfizer's infringement of the GSK Patents through the manufacture, use, offer for sale, sale, and/or importation of Abrysvo in the United States. Among other things, the GSK Patents describe and claim inventions relating to compositions used in RSV vaccines, and methods for preparing those compositions. Upon information and belief, Pfizer knowingly uses GSK's claimed inventions in Abrysvo without permission.

16. RSV is a contagious virus that can lead to serious respiratory illness in individuals of all age groups. In older adults, RSV is a common cause of lower respiratory tract disease, which affects the lungs and can cause life-threatening pneumonia and bronchiolitis. Each year, it is estimated that between 60,000–160,000 older adults in the United States are hospitalized and 6,000–10,000 of them die due to RSV infection.<sup>3</sup> RSV can also be dangerous for some infants and young children. Each year in the United States, an estimated 58,000-80,000 children younger than 5 years old are hospitalized due to RSV infection.<sup>4</sup>

#### **A. FAILURE OF EARLY RSV VACCINES**

17. Before the approval of GSK's groundbreaking Arexvy vaccine, there was no safe or effective RSV vaccine for any population.

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<sup>3</sup> Centers for Disease Control and Prevention, *RSV in Older Adults and Adults with Chronic Medical Conditions* (last updated July 14, 2023), available at <https://www.cdc.gov/rsv/high-risk/older-adults.html>; National Foundation for Infectious Diseases, *RSV: The Annual Epidemic You May Not Know About (But Should)* (Nov. 20, 2016), available at <https://www.nfid.org/rsv-the-annual-epidemic-you-may-not-know-about-but-should/>.

<sup>4</sup> Centers for Disease Control and Preventions, *RSV in Infants and Young Children* (last updated July 21, 2023), available at <https://www.cdc.gov/rsv/high-risk/infants-young-children.html>.

18. Attempts to vaccinate against RSV date back to the mid-1900s. Beginning in the 1960s, numerous vaccination strategies for RSV were tried and failed. Scientists attempted to develop safe and effective RSV vaccines using inactivated virus, live-attenuated virus, and vaccines that target specific proteins in RSV.

19. None of these early vaccine attempts resulted in an RSV vaccine with satisfactory safety and efficacy. Indeed, the vaccination of infants in the 1960s with formalin-inactivated RSV vaccine led to more serious disease following infection, with an increased likelihood of hospitalization and two deaths due to an adverse immune response. Other vaccination strategies likewise presented safety risks or did not produce sufficient immunity.

## **B. DEVELOPMENT OF GSK'S VACCINE AREXVY**

20. GSK's Arexvy was approved by the FDA in May 2023. Exhibit 1 (Arexvy label). It is the first RSV vaccine to be approved anywhere in the world. GSK's Arexvy is the result of more than 15 years of research and development by GSK scientists. It also reflects GSK's significant financial commitment to the development of a safe and effective RSV vaccine, including through the acquisition of RSV development programs at ID Biomedical and Novartis.

21. RSV infects cells by attaching to epithelial cells in the respiratory tract, then fusing with those cells and replicating. The surface of the RSV virus has two glycoproteins that control the attachment and fusion process: glycoprotein G ("RSV G") helps the virus attach to the respiratory cell surface, and glycoprotein F ("RSV F") helps the virus fuse with the respiratory cells.

22. RSV F causes fusion of the virus with the cells in a patient through a process called irreversible protein refolding. Before the virus attaches to the respiratory cells, RSV F protein exists on the surface of the virus in a form referred to as a "preF" conformation, or "RSVpreF".

After the virus attaches to the cell surface, RSVpreF undergoes an irreversible change in shape to a form referred to as “postF” conformation, or “RSVpostF”. This change in the shape of RSV F brings the virus and cell surface together to initiate fusion of the virus and the cell.

23. Beginning in the early 2000s, GSK scientists, including one or more of the named inventors of the GSK Patents, began working on the development of a RSVPreF antigen. Their focus on the RSVPreF antigen was a significant innovation that departed from prevailing vaccination strategies that did not distinguish between the RSVPreF and RSVPostF conformation. GSK scientists realized that previous vaccines using the RSVPostF conformation induced an immune response only to the RSVPostF conformation, which led to limited or no efficacy. Beginning in the mid-2000s and continuing into this decade, GSK scientists worked to develop a RSVPreF antigen that targets the RSVPreF conformation present on the virus before it attaches to the cell surface. GSK discovered and developed innovative solutions for creating RSVPreF antigens that eventually led to the basis of the world’s first ever approved RSV vaccine, GSK’s Arexvy.

24. On June 10, 2022, GSK announced the results of the Phase III clinical studies on its RSV vaccine. These results showed exceptional protection for older adults from the serious consequences of RSV infection, such as pneumonia, hospitalization, and death.

25. On May 3, 2023, the FDA approved GSK’s Arexvy as the world’s first RSV vaccine. Arexvy is an injection that contains “lyophilized recombinant respiratory syncytial virus glycoprotein F stabilized in pre-fusion conformation (RSVPreF3) as the antigen component...” Exhibit 1 (Arexvy label) at 8. Arexvy is indicated for active immunization for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older.

26. GSK's Arexvy is a commercial embodiment of the compositions claimed in at least the '002 Patent, '239 Patent, and '284 Patent.

### **C. PFIZER'S INFRINGING RSV VACCINE**

27. Upon information and belief, Pfizer began the project that led to Abrysvo no earlier than 2013, at least seven years after GSK started its RSV program. Just like Arexvy, Abrysvo is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older. Abrysvo is an injection consisting of "Lyophilized Antigen Component" that contains recombinant RSVPreF proteins. Exhibit 2 (Abrysvo label) at 9.

28. Abrysvo for older adults was approved by the FDA for use in the United States on May 31, 2023. According to the prescribing information for Abrysvo, Pfizer manufactures Abrysvo in the United States under U.S. License No. 2001. Pfizer distributes Abrysvo through its division, Pfizer Labs.

29. Abrysvo is currently also under FDA review for the prevention of medically attended lower respiratory tract disease (MA-LRTD) and severe MA-LRTD caused by RSV in infants from birth up to six months of age by active immunization of pregnant individuals. The FDA has set a Prescription Drug User Fee Act ("PDUFA") date in August 2023 for a decision on that indication.<sup>5</sup>

30. On July 21, 2023, Pfizer also announced that the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") granted a marketing

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<sup>5</sup> Press Release, Pfizer, Pfizer's ABRYSVO™ Receives Recommendation for Use in Older Adults from Advisory Committee on Immunization Practices (June 22, 2023), *available at* <https://www.pfizer.com/news/announcements/pfizers-abrysvotm-receives-recommendation-use-older-adults-advisory-committee>.

authorization for Abrysvo for both older adults and maternal immunization to help protect infants. The European Commission (“EC”) will take the CHMP’s recommendation under advisement to decide whether to approve Abrysvo in all 27 member states of the European Union.<sup>6</sup>

31. Upon information and belief, Pfizer offers Abrysvo for sale to healthcare providers, retail pharmacies, hospitals, and health centers in the U.S., including in Delaware. On May 31, 2023, Pfizer announced that Abrysvo will be available in the third quarter of 2023. As of July 19, 2023, Abrysvo has been administered to at least one patient.

32. Pfizer’s manufacture, use, offer for sale, sale, and/or importation of Abrysvo infringes one or more claims of the GSK Patents. Upon information and belief, Pfizer knowingly uses the inventions claimed in the GSK Patents without permission.

### **THE GSK PATENTS**

#### **A. U.S. PATENT NO. 8,563,002**

33. GSK Biologicals is the lawful owner by assignment of the ’002 Patent, which is entitled “Recombinant RSV Antigens” and was duly and legally issued by the U.S. Patent and Trademark Office on October 22, 2013. A true and correct copy of the ’002 Patent is attached as Exhibit 3.

34. The claims of the ’002 Patent are valid and enforceable.

35. The ’002 Patent claims, *inter alia*, RSV antigens with a heterologous trimerization domain.

36. The ’002 Patent will expire no earlier than October 1, 2029.

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<sup>6</sup> Press Release, Pfizer, Pfizer Receives Positive CHMP Opinion for RSV Vaccine Candidate to Help Protect Infants through Maternal Immunization and Older Adults (July 21, 2023), *available at* <https://www.pfizer.com/news/announcements/pfizer-receives-positive-chmp-opinion-rsv-vaccine-candidate-help-protect-infants>.

37. GSK Biologicals, as the owner of the entire right, title, and interest in the '002 Patent, possesses the right to sue for infringement of the '002 Patent.

**B. U.S. PATENT NO. 11,261,239**

38. GSK Biologicals is the lawful owner by assignment of the '239 Patent, which is entitled "RSV F Protein Compositions and Methods for Making Same" and was duly and legally issued by the U.S. Patent and Trademark Office on March 1, 2022. A true and correct copy of the '239 Patent is attached as Exhibit 4.

39. The claims of the '239 Patent are valid and enforceable.

40. The '239 Patent claims, *inter alia*, immunogenic RSV F compositions with a T4 foldon domain of SEQ ID No:19.

41. The '239 Patent will expire no earlier than November 20, 2030.

42. GSK Biologicals, as the owner of the entire right, title and interest in the '239 Patent, possesses the right to sue for infringement of the '239 Patent.

**C. U.S. PATENT NO. 11,629,181**

43. GSK Biologicals is the lawful owner by assignment of the '181 Patent, which is entitled "RSV F Protein Compositions and Methods for Making Same" and was duly and legally issued by the U.S. Patent and Trademark Office on April 18, 2023. The '181 Patent is a continuation of the '239 Patent. A true and correct copy of the '181 Patent is attached as Exhibit 5.

44. The claims of the '181 Patent are valid and enforceable.

45. The '181 Patent claims, *inter alia*, immunogenic RSV F compositions with a trimerizing sequence from T4 fibrin.

46. The '181 Patent will expire no earlier than July 15, 2030.

47. GSK Biologicals, as the owner of the entire right, title and interest in the '181 Patent, possesses the right to sue for infringement of the '181 Patent.

**D. U.S. PATENT NO. 11,655,284**

48. GSK Biologicals is the lawful owner by assignment of the '284 Patent, which is entitled "RSV F Protein Compositions and Methods for Making Same" and was duly and legally issued by the U.S. Patent and Trademark Office on May 23, 2023. A true and correct copy of the '284 Patent is attached as Exhibit 6.

49. The claims of the '284 Patent are valid and enforceable.

50. The '284 Patent claims, *inter alia*, polypeptides with trimerizing sequences from T4 fibrin.

51. The '284 Patent will expire no earlier than July 15, 2030.

52. GSK Biologicals, as the owner of the entire right, title and interest in the '284 Patent, possesses the right to sue for infringement of the '284 Patent.

**PFIZER'S KNOWLEDGE OF THE GSK PATENTS**

53. Upon information and belief, Pfizer has had knowledge of at least the '002 Patent since at least October 2019, when Pfizer filed an opposition in the European Patent Office claiming that a European counterpart to the '002 Patent is invalid. In June 2022, Pfizer also filed an action against GSK in the Royal Courts of Justice in London, claiming that European counterparts to both the '002 and '239 Patents are invalid.

54. Additionally, upon information and belief, because Arexvy and Abrysvo are the only vaccines FDA-approved to immunize older adults against RSV, Pfizer either knew or should have known that its actions with respect to Abrysvo infringe the GSK Patents.

**COUNT I -- INFRINGEMENT OF THE '002 PATENT UNDER 35 U.S.C. § 271**

55. GSK incorporates each of the preceding paragraphs 1-54 as if fully set forth herein.

56. Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Abrysvo in the United States, and/or the importation of Abrysvo into the United States. Pursuant to 35 U.S.C. § 271, these acts constitute infringement, either literally or under the doctrine of equivalents, of one or more claims of the '002 Patent.

57. Pfizer infringes the '002 Patent by making, using, offering to sell, selling, and/or importing Abrysvo in or into the United States and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c). Specifically, and upon information and belief, the composition of Abrysvo, and the way it is made, used, and sold as described in the prescribing information for Abrysvo, does and will infringe every limitation of at least claim 1 of the '002 Patent, either literally or under the doctrine of equivalents. Pfizer's Abrysvo contains a recombinant RSV antigen which comprises an F2 domain and F1 domain of an RSV F protein polypeptide with no intervening furin cleavage site. *See Exhibit 2 (Abrysvo label) at 9* ("The RSV preF A and RSV preF B recombinant proteins are expressed in genetically engineered Chinese Hamster Ovary cell lines...."). According to a paper published by Pfizer scientists, the RSV antigen in Pfizer's vaccine also includes a T4 foldon domain positioned C-terminal to the F1 domain, which is a heterologous trimerization domain. *See Exhibit 7 (Ye Che et al., Rational Design of a Highly Immunogenic Prefusion-Stabilized F Glycoprotein Antigen for a Respiratory Syncytial Virus Vaccine, Sci. Transl. Med. (Ahead of Print Apr. 6, 2023) (DOI: 10.1126/scitranslmed.ade6422) ("Che")) at 2* ("We ... selected stabilizing mutations for a bivalent RSV prefusion F vaccine candidate that is now in advanced-stage clinical trials (NCT04424316 and NCT05035212)."); *id.* ("Suggested amino acid substitutions identified from this analysis were

introduced into the ectodomain, which was fused at its C terminus to a T4 fibrin foldon trimerization domain (20).”).

58. Pfizer also has induced infringement, and continues to induce infringement, of one or more claims of the '002 Patent. Pfizer knowingly and intentionally induces third parties to infringe the '002 Patent, including health care providers, by selling or otherwise supplying Abrysvo with the knowledge and intent that third parties will use Abrysvo to infringe the '002 Patent. Pfizer knowingly and intentionally provides third parties with instructions on how to administer Abrysvo in a way that infringes the '002 Patent. For example, Abrysvo's package insert explains how to prepare Abrysvo for administration and encourages medical providers to prescribe Abrysvo to actively immunize patients for the prevention of LRTD caused by RSV in individuals 60 years of age and older. *See generally* Exhibit 2 (Abrysvo label).

59. Pfizer also has contributed and will contribute to the infringement by third parties of one or more claims of the '002 Patent by making, using, offering to sell, selling, and/or importing Abrysvo in or into the United States, knowing that Abrysvo is especially made or adapted to infringe the '002 Patent and knowing that Abrysvo is not a staple of commerce suitable for non-infringing use.

60. Upon information and belief, Pfizer has had actual or constructive knowledge of the '002 Patent since at least the approval date of Abrysvo.

61. Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing of Abrysvo does and will constitute infringement of the '002 Patent.

62. Pfizer's infringement of the '002 Patent has been, and continues to be, willful and deliberate since at least the approval date of Abrysvo because, despite an objectively high

likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Abrysvo in or into the United States.

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

**COUNT II -- INFRINGEMENT OF THE '239 PATENT UNDER 35 U.S.C. § 271**

64. GSK incorporates each of the preceding paragraphs 1-63 as if fully set forth herein.

65. Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Abrysvo in the United States, and/or the importation of Abrysvo into the United States. These acts constitute infringement, either literally or under the doctrine of equivalents, of one or more claims of the '239 Patent pursuant to 35 U.S.C. § 271.

66. Pfizer infringes the '239 Patent by making, using, offering to sell, selling, and/or importing Abrysvo in or into the United States and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c). Specifically, and upon information and belief, the composition of Abrysvo, and the way it is made, used, and sold as described in the prescribing information for Abrysvo, does and will infringe every limitation of at least claim 1 of the '239 Patent, either literally or under the doctrine of equivalents. Pfizer's Abrysvo is an immunogenic composition that contains a recombinant RSV antigen, which comprises an RSV F protein ectodomain. *See* Exhibit 2 (Abrysvo label) at 9 ("ABRYSVO induces an immune response against RSV pre F that protects against lower respiratory tract disease caused by RSV."); *id.* ("The RSV preF A and RSV preF B recombinant proteins are expressed in genetically engineered Chinese Hamster Ovary cell lines...."). On information and belief, the RSV antigen in Pfizer's vaccine also includes a T4 foldon domain positioned C-terminal to the F1 domain, which comprises the amino acid sequence of SEQ ID NO:19, or a sequence equivalent thereto. *See* Exhibit 7 (Che) at 2 ("Suggested amino acid substitutions identified from this analysis were

introduced into the ectodomain, which was fused at its C terminus to a T4 fibrin foldon trimerization domain (20).”).

67. Upon information and belief, Pfizer has had actual or constructive knowledge of the '239 Patent since at least the approval date of Abrysvo.

68. Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing of Abrysvo does and will constitute infringement of the '239 Patent.

69. Pfizer's infringement of the '239 Patent has been, and continues to be, willful and deliberate since at least the approval date of Abrysvo because, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Abrysvo in or into the United States.

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

### **COUNT III -- INFRINGEMENT OF THE '181 PATENT UNDER 35 U.S.C. § 271**

71. GSK incorporates each of the preceding paragraphs 1-70 as if fully set forth herein.

72. Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Abrysvo in the United States, and/or the importation of Abrysvo into the United States. These acts constitute infringement, either literally or under the doctrine of equivalents, of one or more claims of the '181 Patent pursuant to 35 U.S.C. § 271.

73. Pfizer infringes the '181 Patent by making, using, offering to sell, selling, and/or importing Abrysvo in or into the United States and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c). Specifically, and upon information and belief, the composition of Abrysvo, and the way it is made, used, and sold as described in the prescribing information for Abrysvo, does and will infringe every limitation of at least claim 1 of

'181 Patent, either literally or under the doctrine of equivalents. Pfizer's Abrysvo is an immunogenic composition comprised of a recombinant RSV F polypeptide of an RSV A subgroup and RSV B subgroup. *See* Exhibit 2 (Abrysvo label) at 9 ("ABRYSVO induces an immune response against RSV pre-F that protects against lower respiratory tract disease caused by RSV."); *id.* ("The antigen component contains recombinant RSV preF A and RSV preF B."). On information and belief, the RSV preF A and RSV preF B polypeptides comprise a T4 foldon domain, which is a trimerizing sequence from bacteriophage T4 fibrin. *See* Exhibit 7 (Che) at 2 ("Suggested amino acid substitutions identified from this analysis were introduced into the ectodomain, which was fused at its C terminus to a T4 fibrin foldon trimerization domain (20)"). On information and belief, the RSV preF A and RSV preF B polypeptides are ectodomain vaccine antigens that do not comprise a transmembrane region or cytoplasmic tail. *Id.* at 6 ("[T]he 847 prefusion-stabilizing mutations were introduced onto these strain backbones to produce the 847A and 847B RSV F ectodomain vaccine antigens, which are co-formulated in the bivalent vaccine candidate, RSVpreF.").

74. Upon information and belief, Pfizer has had actual or constructive knowledge of the '181 Patent since at least the approval date of Abrysvo.

75. Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing of Abrysvo does and will constitute infringement of the '181 Patent.

76. Pfizer's infringement of the '181 Patent has been, and continues to be, willful and deliberate since at least the approval date of Abrysvo because, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Abrysvo in or into the United States.

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

**COUNT IV -- INFRINGEMENT OF THE '284 PATENT UNDER 35 U.S.C. § 271**

78. GSK incorporates each of the preceding paragraphs 1-77 as if fully set forth herein.

79. Pfizer has engaged in the commercial manufacture, use, offer for sale, or sale of Abrysvo in the United States, and/or the importation of Abrysvo into the United States. These acts constitute infringement, either literally or under the doctrine of equivalents, of one or more claims of the '284 Patent pursuant to 35 U.S.C. § 271.

80. Pfizer infringes the '284 Patent by making, using, offering to sell, selling, and/or importing Abrysvo in or into the United States and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c). Specifically, and upon information and belief, the composition of Abrysvo, and the way it is made, used, and sold as described in the prescribing information for Abrysvo, does and will infringe every limitation of at least claim of the '284 Patent, either literally or under the doctrine of equivalents. Pfizer's Abrysvo contains a polypeptide, which comprises an RSV F protein ectodomain. *See* Exhibit 2 (Abrysvo label) at 9 (“The antigen component contains recombinant RSV preF A and RSV preF B.”); Exhibit 7 (Che) at 2 (“Suggested amino acid substitutions identified from this analysis were introduced into the ectodomain, which was fused at its C terminus to a T4 fibrin foldon trimerization domain (20).”), 6 (“[T]he 847 prefusion-stabilizing mutations were introduced onto these strain backbones to produce the 847A and 847B RSV F ectodomain vaccine antigens, which are co-formulated in the bivalent vaccine candidate, RSVpreF.”). On information and belief, the RSV antigen in Pfizer's vaccine also includes a T4 foldon domain, which comprises trimerizing sequence from bacteriophage T4 fibrin. *See id.* at 2 (“Suggested amino acid substitutions identified from this

analysis were introduced into the ectodomain, which was fused at its C terminus to a T4 fibrin foldon trimerization domain (20).”).

81. Upon information and belief, Pfizer has had actual or constructive knowledge of the '284 Patent since at least the approval date of Abrysvo.

82. Pfizer knows or should know that its manufacturing, using, selling, offering to sell, and/or importing of Abrysvo does and will constitute infringement of the '284 Patent.

83. Pfizer's infringement of the '284 Patent has been, and continues to be, willful and deliberate since at least the approval date of Abrysvo because, despite an objectively high likelihood that its actions do and will constitute infringement of a valid patent, Pfizer continues to manufacture, use, sell, offer to sell, and/or import Abrysvo in or into the United States.

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

#### **PRAYER FOR RELIEF**

WHEREFORE, GSK requests the Court grant the following relief:

(a) Judgment that Pfizer's manufacture, use, offer for sale, sale, and/or importation of Abrysvo infringes one or more claims of the GSK Patents;

(b) Judgment awarding GSK damages or other monetary relief, including, without limitation, lost profits and/or reasonable royalties resulting from such Pfizer's infringement of the GSK Patents, increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

(c) Upon a judgment in GSK's favor, an order permanently enjoining Pfizer, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States,

or importing into the United States, Abrysvo for use in adults over 60. Notwithstanding their entitlement to such relief, GSK is not seeking to restrain infringing use of Abrysvo for the prevention of disease caused by RSV in infants by active immunization of pregnant individuals and will seek appropriate damages or other monetary relief in lieu of an injunction for such infringing use.

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

(e) An award of GSK's fees and costs for this litigation; and

(f) Such further and other relief as this Court deems just and proper, including but not limited to any appropriate relief under Title 35.

### **DEMAND FOR JURY TRIAL**

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

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