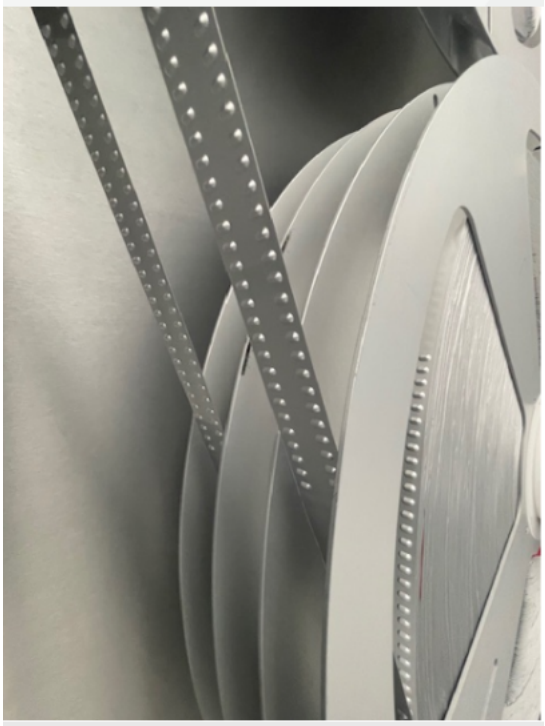


Ex. K.

63. Transpire sent GSK a notice letter, dated August 12, 2025, stating that Transpire had submitted the Transpire ANDA seeking approval to manufacture, import, use, market, and/or sell the Proposed ANDA Product prior to the expiration of the '721 patent, '242 patent, and '281 patent (the "Paragraph IV Notice Letter").

64. GSK received the Notice Letter on August 13, 2025.

65. Transpire's Paragraph IV Notice Letter asserts, *inter alia*, that the '721 patent, '242 patent, and '281 patent are not infringed. The Paragraph IV Notice Letter includes no substantive allegations that any claims of the Patents-in-Suit are invalid.

66. The Paragraph IV Notice Letter included an offer of confidential access to the Transpire ANDA pursuant to 21 U.S.C. § 355(j)(5)(C). The offer only committed to provide unspecified portions of the ANDA, did not include an offer of samples for inspection, and was subject to unreasonably restrictive confidentiality provisions. Efforts to negotiate the terms of

the offer of confidential access and to obtain clarity on the contents of the materials that Transpire would produce were unsuccessful.

67. Transpire's submission of the Transpire ANDA to the FDA, including any amendments or supplements thereto, and any commercial manufacture or sale by Transpire of the Proposed ANDA Product, constitutes infringement of the Patents-in-Suit, as detailed below.

68. On information of belief, Transpire's manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Proposed ANDA Product and/or the Transpire Inhaler Product infringe the Patents-in-Suit, as detailed below.

69. GSK filed this lawsuit before the expiration of forty-five days from the date GSK received Transpire's Paragraph IV Notice Letter.

Transpire's Infringing Products Violate GSK's Rights in the Ellipta Trade Dress

70. Long after GSK developed exclusive rights in the Ellipta Trade Dress and long after GSK obtained federal registrations protecting the Ellipta Trade Dress, Transpire began marketing and selling its own lookalike Infringing Products.

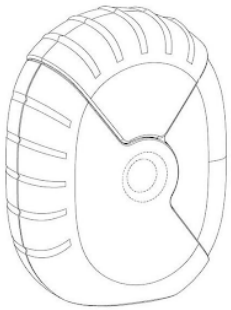
71. Including through its website at *transpirebio.com*, Transpire markets the lookalike Infringing Products as an "inhalation platform" to be used to deliver third-party pharmaceutical products:

72. According to Transpire, Transpire's "inhalation platforms" are "fully developed," "have wide applicability," and "can support small molecules, polypeptides, protein, oligoneucleotides, biologics, and vaccines." Ex. K.

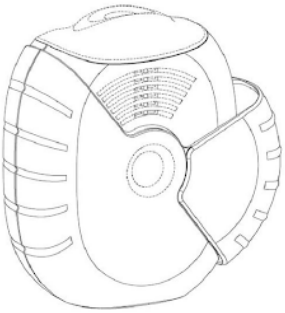
73. Upon information and belief, Transpire further plans to use its Infringing Products to administer its generic version of BREO.

74. Upon information and belief, Transpire's marketing and sale of the lookalike Infringing Products is a deliberate attempt to capitalize on the immense goodwill associated with the Ellipta Trade Dress and to mislead the public into believing that the Infringing Products come from or are otherwise associated with GSK.

75. On or about January 25, 2023, Transpire filed U.S. Application Serial Nos. 97/767,006 and 97/766,996 (the "Transpire Applications") under Section 1(b) of the Lanham Act based on an alleged *bona fide* intent to use the below marks (together, the "Infringing Inhaler Design") in commerce in connection with, *inter alia*, inhaled pharmaceutical preparations in International Class 5 and inhalers sold empty in International Class 10:



App. Serial No. 97/767,006



App. Serial No. 97/766,996

76. On or about November 12, 2024, Transpire filed Amendments to Allege Use in both Transpire Applications, claiming use of the Infringing Inhaler Design in United States commerce at least as early as September 3, 2024.

77. On information and belief, Transpire has manufactured, advertised, offered for sale, sold, distributed, imported, and/or exported Infringing Products bearing the Infringing Inhaler Design in United States commerce.

78. Transpire's use of an Infringing Inhaler Design that so closely resembles GSK's Ellipta Trade Dress unfairly and unlawfully wrests from GSK control over its reputation.

79. The goodwill that GSK has built up in the Ellipta Trade Dress is therefore put at risk by Transpire's appropriation and use of the Infringing Inhaler Design in connection with the Infringing Products.

80. On information and belief, Transpire's infringement of the Ellipta Trade Dress is deliberate, willful, and undertaken with full knowledge of GSK's prior exclusive rights, with knowledge of the reputation and goodwill of the Ellipta Trade Dress, and with knowledge that the Ellipta Trade Dress is associated exclusively with GSK and GSK's ELLIPTA inhaler. Given that Transpire intends to use the Infringing Products in connection with marketing, selling, distributing, and administering its generic version of BREO, there is no question that Transpire has long been aware of the Ellipta Trade Dress used in connection with BREO ELLIPTA.

81. Indeed, Transpire has actual knowledge of GSK's rights, as the GSK Registrations have been cited against Transpire at the Trademark Office.

82. Transpire's actions even create dangerous potential for actual physical harm to patients. Because the Ellipta Trade Dress is so unique and distinctive, doctors who prescribe medications administered through the ELLIPTA inhaler, the pharmacists who select and dispense these products, and the consumers who use the products can easily differentiate the Ellipta Portfolio Products from products offered by competitors. Transpire's continued use of an Infringing Inhaler Design nearly identical to the protected Ellipta Trade Dress is likely to cause confusion among patients, doctors, pharmacists and all other relevant consumers, including because all such consumers will naturally assume that the Infringing Products sold by Transpire under the Infringing Inhaler Design emanate from or are authorized by, licensed by, endorsed by, associated with, or otherwise connected with GSK or its renowned ELLIPTA products.

83. Transpire's planned use of its Infringing Products in connection with marketing, sale, and distribution of a generic version of BREO will lead relevant consumers to conclude that the Infringing Products contain and dispense the BREO pharmaceutical product rather than a generic thereof.

84. But Transpire's ongoing marketing and sale of its Infringing Products as a vessel for administration of *unknown* third-party drugs is equally dangerous, given the prospect that a patient prescribed an ELLIPTA inhaler may instead receive – or grab out of his or her medicine cabinet – one of Transpire's Infringing Products and thereby receive the wrong drug product altogether.

85. Upon information and belief, despite its awareness of these potential risks, Transpire intentionally designed its Infringing Products to look just like ELLIPTA inhalers in

order to capitalize on the goodwill in the Ellipta Trade Dress and in a deliberate effort to mislead patients, pharmacists, and doctors alike into believing that GSK and Transpire are somehow associated or affiliated or that GSK has authorized Transpire's use of the Ellipta Trade Dress – which it has not.

COUNT I
INFRINGEMENT OF THE '721 PATENT

86. GSK incorporates Paragraphs 1 through 47 and 57 through 69 as if fully set forth herein.

87. The submission of the Transpire ANDA to the FDA, including the Paragraph IV Certification submitted therewith, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Proposed ANDA Product prior to the expiration of the '721 patent, constitutes infringement by Transpire of the '721 patent under 35 U.S.C. § 271(e)(2)(A).

88. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product by Transpire before the expiration of the '721 patent would constitute infringement by Transpire of the '721 patent under 35 U.S.C. §§ 271(a)-(c).

89. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, if Transpire's Proposed ANDA Product is approved, Transpire will make, use, offer for sale, sell, market, distribute, or import Transpire's Proposed ANDA Product, comprising fluticasone furoate and vilanterol trifenatate, and would infringe at least, by way of example, claims 1, 12, 28-34, 49, 50, 52, and 57-61 of the '721 patent, which recite as follows:

1. A pharmaceutical product consisting essentially of:

(a) a dry powder formulation consisting essentially of Compound (I), which is 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxyl}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol or a pharmaceutically acceptable salt thereof, present in micronized form and in a dose selected from the group consisting of 12.5, 25, and 50 mcg, calculated as the free base, and wherein Compound (I) is in admixture with lactose and 0.6 to 2% w/w of magnesium stearate, and

(b) a dry powder formulation consisting essentially of Compound (II), which is 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester, and lactose.

12. A pharmaceutical product consisting essentially of:

(a) a dry powder formulation consisting essentially of Compound (I), which is 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxyl}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol, triphenyl acetate present in micronized form and in a dose of 25 mcg, calculated as the free base, and wherein Compound (I) is in admixture with lactose and 0.75 to 1.5% w/w of magnesium stearate, and

(b) a dry powder formulation consisting essentially of Compound (II), which is 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester present in a dose of 100 mcg and lactose.

28. A method for the treatment of a respiratory disease, comprising administering to a patient in need thereof, a pharmaceutical product according to claim 1.

29. A method according to claim 28 wherein the disease is selected from the group consisting of chronic obstructive pulmonary disease, chronic bronchitis, asthma, chronic respiratory obstruction, pulmonary fibrosis, pulmonary emphysema and allergic rhinitis.

30. A method according to claim 28 wherein the disease is asthma.

31. A method according to claim 28 wherein the disease is chronic obstructive pulmonary disease.

32. A method according to claim 28 wherein administration is via inhalation by the mouth or nose.

33. A method according to claim 28 wherein the dry powder formulation of Compound (I) and the dry powder formulation of Compound (II) are administered simultaneously.

34. A method according to claim 28 wherein the pharmaceutical product is administered once per day.

49. A pharmaceutical product consisting of:

(a) a dry powder formulation of Compound (I), which is 4-{(1 R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol or a pharmaceutically acceptable salt thereof, present in micronized form and in a dose selected from the group consisting of 12.5, 25, and 50 mcg, calculated as the free base, and wherein Compound (I) is in admixture with lactose and 0.6 to 2% w/w of magnesium stearate, and

(b) a dry powder formulation of Compound (II), which is 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester, and lactose.

50. A pharmaceutical product consisting of:

(a) a dry powder formulation of Compound (I), which is 4-{(1 R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol triphenyl acetate present in micronized form and in a dose of 25 mcg, calculated as the free base, and wherein Compound (I) is in admixture with lactose and 0.75 to 1.5% w/w of magnesium stearate, and

(b) a dry powder formulation of Compound (II), which is 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester present in a dose of 100 mcg and lactose.

52. A method for the treatment of a respiratory disease comprising administering to a patient in need thereof a pharmaceutical product according to claim 49.

57. A method for the treatment of a respiratory disease comprising administering to a patient in need thereof a pharmaceutical product according to claim 50.

58. A method according to claim 57 wherein the disease is asthma.

59. A method according to claim 57 wherein the disease is chronic obstructive pulmonary disease.

60. A method according to claim 57 wherein the dry powder formulation of Compound (I) and the dry powder formulation of Compound (II) are administered simultaneously.

> 61. A method according to claim 57 wherein the pharmaceutical product is administered once per day.

90. On information and belief, Transpire's Proposed ANDA Product will have the same active ingredients as BREO ELLIPTA and will substantively copy the BREO ELLIPTA Label with respect to the fluticasone furoate and vilanterol inhalation powder, 100 mcg/25 mcg strength. *See* 21 C.F.R. §§ 314.94(a)(5), (a)(8)(iii)-(iv). Accordingly, on information and belief, Transpire's Proposed ANDA Product will contain as dry powder active ingredients: (1) fluticasone furoate, also referred to as 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester, and additionally referred to as (6α,11β,16α,17α)-6,9-difluoro-17-{[(fluoro-methyl)thio]carbonyl}-11-hydroxy-16-methyl-3- oxoandrosta-1,4-dien-17-yl 2-furancarboxylate, and (2) vilanterol trifenatate, also referred to as 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxyl}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol, triphenyl acetate, and additionally referred to as triphenylacetic acid-4-{(1R)-2-[(6-{2-[2,6- dicholorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol (1:1).

91. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, Transpire's Proposed ANDA Product comprises a dry powder formulation of vilanterol trifenatate, present in a micronized form, and in a dose of 25 mcg, calculated as the free base, which is in admixture with lactose and 0.75 to 1.5% w/w magnesium stearate, and (2) a dry powder formulation of fluticasone furoate present in a dose of 100 mcg and lactose. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire' proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product will satisfy each of the recited elements of

the pharmaceutical product recited in at least claims 1, 12, and 49-50 of the ’721 patent, and thus directly infringes at least claims 1, 12, and 49-50 of the ’721 patent, either literally or under the doctrine of equivalents.

92. On information and belief, the proposed label for Transpire’s Proposed ANDA Product, including its indication to treat patients with COPD, chronic bronchitis, emphysema, and/or asthma, would actively direct, instruct, recommend, encourage, and/or promote physicians, prescribers, and/or patients to administer Transpire’s Proposed ANDA Product to such patients.

93. On information and belief, the proposed label for Transpire’s Proposed ANDA Product, including its instructions to dose the Proposed ANDA Product as one actuation once daily by oral inhalation, would actively direct, instruct, recommend, encourage, and/or promote physicians, prescribers, and/or patients to administer Transpire’s Proposed ANDA Product once via inhalation by the mouth or nose once per day.

94. On information and belief, Transpire’s Proposed ANDA Product administers the recited dry powder formulation of fluticasone furoate and the recited dry powder formulation of vilanterol trifenatate in Transpire’s Proposed ANDA Product simultaneously.

95. On information and belief, if the FDA were to approve Transpire’s Proposed ANDA, Transpire’s commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product, including administration of Transpire’s Proposed ANDA Product according to the label instructions, would cause patients, physicians, prescribers, and/or other healthcare providers to directly infringe at least claims 28-34, 52, and 57-61 of the ’721 patent. Transpire would actively induce and contribute to such direct infringement.

96. Transpire has knowledge of the claims of the '721 patent as evidenced at least by Transpire's Paragraph IV Notice Letter. Despite this knowledge, Transpire has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing (including marketing Transpire's Proposed ANDA Product as a generic substitute for BREO ELLIPTA to be used and administered in the same manner as BREO ELLIPTA), distribution, and/or importation of Transpire's Proposed ANDA Product with the proposed labeling to be included for the Proposed ANDA Product, immediately and imminently upon approval of ANDA No. 218914. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, by engaging in the forgoing activities, Transpire specifically intends to infringe the '721 patent.

97. On information and belief, Transpire's specific intent to actively induce and/or contribute to infringement of at least claims 1, 12, 28-34, 49-50, and 52, 57-61 of the '721 patent includes Transpire's decision to proceed with its plan to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product, despite being aware that the proposed labeling to be included for the Proposed ANDA Product instructs, directs, recommends, encourages, and/or promotes direct infringement of the '721 patent.

98. On information and belief, and with full knowledge of the '721 patent, Transpire intends to and will actively induce infringement of the '721 patent when Transpire's Proposed ANDA Product is approved and will do so immediately and imminently upon approval.

99. BREO ELLIPTA and any corresponding generic fluticasone furoate and vilanterol trifenatate inhalation powder product is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1, 12, 28-34, 49-50, 52, and 57-61 of the '721 patent. On information and belief, and subject to GSK's ongoing investigation and discovery

efforts, Transpire, with full knowledge of the ’721 patent, knows that its Proposed ANDA Product is especially adapted for use in a manner that infringes the ’721 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1, 12, 28-34, 49-50, 52, and 57-61 of the ’721 patent.

100. Any launch by Transpire of the Proposed ANDA Product before expiration of the ’721 patent would cause GSK to suffer immediate and irreparable harm.

101. Unless Transpire is enjoined from infringing the ’721 patent, actively inducing infringement of the ’721 patent, and contributing to the infringement of others of the ’721 patent, GSK will suffer irreparable injury. GSK has no adequate remedy at law.

102. Transpire’s infringement of the ’721 patent is willful.

COUNT II
DECLARATORY JUDGMENT OF
INFRINGEMENT OF THE ’721 PATENT

103. GSK incorporates Paragraphs 1 through 47 and 57 through 69 as if fully set forth herein.

104. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

105. On information and belief, Transpire’s submission of its ANDA to FDA seeking approval to market its Proposed ANDA Product along with Transpire’s preparations to launch, market, and sell its Proposed ANDA Product upon FDA approval, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Transpire has directly or indirectly infringed or will directly or indirectly infringe at least one claim of each of the asserted patents by engaging in the commercial manufacture, use, offer to sell, sale or importation of

Transpire's Proposed ANDA Product, or by actively inducing or contributing to that infringement of at least one claim of the '721 patent prior to its expiration.

106. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product by Transpire before the expiration of the '721 patent would constitute infringement by Transpire of the '721 patent under 35 U.S.C. §§ 271(a)-(c).

107. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, if Transpire's Proposed ANDA Product is approved, Transpire will make, use, offer for sale, sell, market, distribute, and/or import Transpire's Proposed ANDA Product, comprising fluticasone furoate and vilanterol trifenatate, and would infringe at least, by way of example, claims 1, 12, 28-34, 49, 50, 52, and 57-61 of the '721 patent, which recite as follows:

1. A pharmaceutical product consisting essentially of:

> (a) a dry powder formulation consisting essentially of Compound (I), which is 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxyl}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol or a pharmaceutically acceptable salt thereof, present in micronized form and in a dose selected from the group consisting of 12.5, 25, and 50 mcg, calculated as the free base, and wherein Compound (I) is in admixture with lactose and 0.6 to 2% w/w of magnesium stearate, and
>
> (b) a dry powder formulation consisting essentially of Compound (II), which is 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester, and lactose.

12. A pharmaceutical product consisting essentially of:

> (a) a dry powder formulation consisting essentially of Compound (I), which is 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxyl}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol, triphenyl acetate present in micronized form and in a dose of 25 mcg, calculated as the free base, and wherein Compound (I) is in admixture with lactose and 0.75 to 1.5% w/w of magnesium stearate, and

(b) a dry powder formulation consisting essentially of Compound (II), which is 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester present in a dose of 100 mcg and lactose.

28. A method for the treatment of a respiratory disease, comprising administering to a patient in need thereof, a pharmaceutical product according to claim 1.

29. A method according to claim 28 wherein the disease is selected from the group consisting of chronic obstructive pulmonary disease, chronic bronchitis, asthma, chronic respiratory obstruction, pulmonary fibrosis, pulmonary emphysema and allergic rhinitis.

30. A method according to claim 28 wherein the disease is asthma.

31. A method according to claim 28 wherein the disease is chronic obstructive pulmonary disease.

32. A method according to claim 28 wherein administration is via inhalation by the mouth or nose.

33. A method according to claim 28 wherein the dry powder formulation of Compound (I) and the dry powder formulation of Compound (II) are administered simultaneously.

34. A method according to claim 28 wherein the pharmaceutical product is administered once per day.

49. A pharmaceutical product consisting of:

(a) a dry powder formulation of Compound (I), which is 4-{(1 R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol or a pharmaceutically acceptable salt thereof, present in micronized form and in a dose selected from the group consisting of 12.5, 25, and 50 mcg, calculated as the free base, and wherein Compound (I) is in admixture with lactose and 0.6 to 2% w/w of magnesium stearate, and

(b) a dry powder formulation of Compound (II), which is 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester, and lactose.

50. A pharmaceutical product consisting of:

(a) a dry powder formulation of Compound (I), which is 4-{(1 R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol triphenyl acetate present in micronized form and in a

dose of 25 mcg, calculated as the free base, and wherein Compound (I) is in admixture with lactose and 0.75 to 1.5% w/w of magnesium stearate, and

(b) a dry powder formulation of Compound (II), which is 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester present in a dose of 100 mcg and lactose.

52. A method for the treatment of a respiratory disease comprising administering to a patient in need thereof a pharmaceutical product according to claim 49.

57. A method for the treatment of a respiratory disease comprising administering to a patient in need thereof a pharmaceutical product according to claim 50.

58. A method according to claim 57 wherein the disease is asthma.

59. A method according to claim 57 wherein the disease is chronic obstructive pulmonary disease.

60. A method according to claim 57 wherein the dry powder formulation of Compound (I) and the dry powder formulation of Compound (II) are administered simultaneously.

61. A method according to claim 57 wherein the pharmaceutical product is administered once per day.

108. On information and belief, Transpire's Proposed ANDA Product will have the same active ingredients as BREO ELLIPTA and will substantively copy the BREO ELLIPTA Label with respect to the fluticasone furoate and vilanterol inhalation powder, 100 mcg/25 mcg strength. *See* 21 C.F.R. §§ 314.94(a)(5), (a)(8)(iii)-(iv). Accordingly, on information and belief, Transpire's Proposed ANDA Product will contain as dry powder active ingredients: (1) fluticasone furoate, also referred to as 6α, 9α-difluoro-17α-[(2-furanylcarbonyl)oxy]-11β-hydroxy-16α-methyl-3-oxo-androsta-1,4-diene-17β-carbothioic acid S-fluoromethyl ester, and additionally referred to as (6α,11β,16α,17α)-6,9-difluoro-17-{[(fluoro-methyl)thio]carbonyl}-11-hydroxy-16-methyl-3- oxoandrosta-1,4-dien-17-yl 2-furancarboxylate, and (2) vilanterol trifenatate, also referred to as 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxyl}hexyl)amino]-

1-hydroxyethyl}-2-(hydroxymethyl)phenol, triphenyl acetate, and additionally referred to as triphenylacetic acid-4-{(1R)-2-[(6-{2-[2,6- dicholorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol (1:1).

109. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, Transpire's Proposed ANDA Product comprises a dry powder formulation of vilanterol trifenatate, present in a micronized form, and in a dose of 25 mcg, calculated as the free base, which is in admixture with lactose and 0.75 to 1.5% w/w magnesium stearate, and (2) a dry powder formulation of fluticasone furoate present in a dose of 100 mcg and lactose. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire' proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product will satisfy each of the recited elements of the pharmaceutical product recited in at least claims 1, 12, and 49-50 of the '721 patent, and thus directly infringes at least claims 1, 12, and 49-50 of the '721 patent, either literally or under the doctrine of equivalents.

110. On information and belief, the proposed label for Transpire's Proposed ANDA Product, including its indication to treat patients with COPD, chronic bronchitis, emphysema, and/or asthma, would actively direct, instruct, recommend, encourage, and/or promote physicians, prescribers, and/or patients to administer Transpire's Proposed ANDA Product to such patients.

111. On information and belief, the proposed label for Transpire's Proposed ANDA Product, including its instructions to dose the Proposed ANDA Product as one actuation once daily by oral inhalation, would actively direct, instruct, recommend, encourage, and/or promote

physicians, prescribers, and/or patients to administer Transpire's Proposed ANDA Product once via inhalation by the mouth or nose once per day.

112. On information and belief, Transpire's Proposed ANDA Product administers the recited dry powder formulation of fluticasone furoate and the recited dry powder formulation of vilanterol trifenatate in Transpire's Proposed ANDA Product simultaneously.

113. On information and belief, if the FDA were to approve Transpire's Proposed ANDA, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product, including administration of Transpire's Proposed ANDA Product according to the label instructions, would cause patients, physicians, prescribers, and/or other healthcare providers to directly infringe at least claims 28-34, 52, and 57-61 of the '721 patent. Transpire would actively induce and contribute to such direct infringement.

114. Transpire has knowledge of the claims of the '721 patent as evidenced at least by Transpire's Paragraph IV Notice Letter. Despite this knowledge, Transpire has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing (including marketing Transpire's Proposed ANDA Product as a generic substitute for BREO ELLIPTA to be used and administered in the same manner as BREO ELLIPTA), distribution, and/or importation of Transpire's Proposed ANDA Product with the proposed labeling to be included for the Proposed ANDA Product, immediately and imminently upon approval of ANDA No. 218914. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, by engaging in the forgoing activities, Transpire specifically intends to infringe the '721 patent.

115. On information and belief, Transpire's specific intent to actively induce and/or contribute to infringement of at least claims 1, 12, 28-34, 49-50, and 52, 57-61 of the '721 patent

includes Transpire's decision to proceed with its plan to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product, despite being aware that the proposed labeling to be included for the Proposed ANDA Product instructs, directs, recommends, encourages, and/or promotes direct infringement of the '721 patent.

116. On information and belief, and with full knowledge of the '721 patent, Transpire intends to and will actively induce infringement of the '721 patent when Transpire's Proposed ANDA Product is approved and will do so immediately and imminently upon approval.

117. BREO ELLIPTA and any corresponding generic fluticasone furoate and vilanterol trifenatate inhalation powder product is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1, 12, 28-34, 49-50, 52, and 57-61 of the '721 patent. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, Transpire, with full knowledge of the '721 patent, knows that its Proposed ANDA Product is especially adapted for use in a manner that infringes the '721 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1, 12, 28-34, 49-50, 52, and 57-61 of the '721 patent.

118. Any launch by Transpire of the Proposed ANDA Product before expiration of the '721 patent would cause GSK to suffer immediate and irreparable harm.

119. Unless Transpire is enjoined from infringing the '721 patent, actively inducing infringement of the '721 patent, and contributing to the infringement of others of the '721 patent, GSK will suffer irreparable injury. GSK has no adequate remedy at law.

120. Transpire's infringement of the '721 patent would be willful.

121. For at least the above reasons, a definite and concrete controversy exists between GSK and Transpire as to whether Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product prior to the expiration of the '721 patent would infringe the '721 patent. Accordingly, GSK is entitled to a declaratory judgment that it would.

COUNT III
INFRINGEMENT OF THE '242 PATENT

122. GSK incorporates Paragraphs 1 through 47 and 57 through 69 as if fully set forth herein.

123. The submission of the Transpire ANDA to the FDA, including the Paragraph IV Certification submitted therewith, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Proposed ANDA Product prior to the expiration of the '242 patent, constitutes infringement by Transpire of the '242 patent under 35 U.S.C. § 271(e)(2)(A).

124. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product and/or the Transpire Inhaler Product by Transpire before the expiration of the '242 patent would constitute infringement by Transpire of the '242 patent under 35 U.S.C. §§ 271(a)-(c).

125. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, if Transpire's Proposed ANDA Product is approved, Transpire will make, use, offer for sale, sell, market, distribute, and/or import Transpire's Proposed ANDA Product, comprising a medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions, and would infringe at least, by way of example, claims 1-2, and 4-5 of the '242 patent.

126. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, Transpire makes, offers for sale, sells, markets, distributes, and/or imports the Transpire Inhaler Product, comprising a medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions, and infringes at least, by way of example, claims 1-2 of the '242 patent.

127. Claims 1-2 and 4-5 of the '242 patent recite as follows:

> 1. A medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions, said medicament dispenser comprising
>
> > (a) a dispensing mechanism actuable for dispensing the distinct medicament portions carried by said at least one medicament carrier;
> >
> > (b) a mouthpiece; and
> >
> > (c) a cover for said mouthpiece, said cover being movably mounted to the dispenser for sequential movement from a first position, in which said mouthpiece is covered, to a second position, in which said mouthpiece is part-uncovered, to a third position in which said mouthpiece is uncovered;
> >
> > wherein said cover is adapted to couple with said dispensing mechanism such that movement of the cover from the first position to the second position does not result in actuation of the dispensing mechanism, but any further movement of the cover from the second position to the third position results in actuation of the dispensing mechanism.
>
> 2. A medicament dispenser according to claim 1 including a plurality of said medicament carriers each carrying multiple distinct medicament dose portions.
>
> 4. A medicament dispenser according to claim 2, wherein said plurality of said medicament carriers consists of a first and a second medicament carrier, each of said medicament carriers carrying distinct medicament portions in powder form, each of said medicament dose portions of said first medicament carrier comprising a bronchodilator as the active medicament component and each of said medicament dose portions of said second medicament carrier comprising an anti-inflammatory as the active medicament component.

> 5. A medicament dispenser according to claim 4, wherein said bronchodilator is a beta-agonist and said anti-inflammatory is a corticosteroid.

128. On information and belief, Transpire's Proposed ANDA Product will have the same route of administration and dosage form as BREO ELLIPTA, which comprises an inhaler device. *See* 21 C.F.R. § 314.94(a)(6). Accordingly, on information and belief, Transpire's Proposed ANDA Product will comprise an inhaler device.

129. Additionally, on information and belief, Transpire's Proposed ANDA Product will have the same active ingredients as BREO ELLIPTA and will substantively copy the BREO ELLIPTA Label with respect to the fluticasone furoate and vilanterol inhalation powder, 100 mcg/25 mcg strength. *See* 21 C.F.R. §§ 314.94(a)(5), (a)(8)(iii)-(iv). Accordingly, on information and belief, Transpire's Proposed ANDA Product will contain as dry powder active ingredients: (1) fluticasone furoate, which is a bronchodilator, and more specifically a beta-agonist; and (2) vilanterol trifenatate, which is an anti-inflammatory, and more specifically a corticosteroid.

130. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions. *See, e.g.*, Ex. K ("We have developed commercial scale, clinical-stage inhalation formulation technologies and delivery platforms that are fully customizable to different clinical applications."); *id.* ("Our inhalation technology platforms have wide applicability and can support small molecules, polypeptides, protein, oligonucleotides, biologics, and vaccines."); *id.* (Rollingstar inhalation device pictured).

131. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser, which comprises a dispensing mechanism

actuable for dispensing the distinct medicament portions carried by said at least one medicament carrier. Exs. K, N (demonstrating use of Transpire's Rollingstar dry powder inhaler).

132. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser which comprises a mouthpiece. Ex. K (Rollingstar inhaler mouthpiece).

133. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser which comprises a cover for said mouthpiece, said cover being movably mounted to the dispenser for sequential movement from a first position, in which said mouthpiece is covered, to a second position, in which said mouthpiece is part-uncovered, to a third position in which said mouthpiece is uncovered. Ex. K (Rollingstar inhaler in closed position, with mouthpiece covered); *id.* (Rollingstar inhaler mouthpiece uncovered when in use).

134. On information and belief, the cover of Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser which is adapted to couple with said dispensing mechanism such that movement of the cover from the first position to the second position does not result in actuation of the dispensing mechanism, but any further movement of the cover from the second position to the third position results in actuation of the dispensing mechanism. Ex. K (Rollingstar inhaler in closed position, with mouthpiece covered); *id.* (Rollingstar inhaler mouthpiece uncovered when in use).

135. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire

Inhaler Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 1 of the ’242 patent, and thus directly infringes claim 1 of the ’242 patent, either literally or under the doctrine of equivalents.

136. On information and belief, Transpire’s Proposed ANDA Product and the Transpire Inhaler Product comprise the medicament dispenser of claim 1, and includes a plurality of said medicament carriers each carrying multiple distinct medicament dose portions. Accordingly, on information and belief, and subject to GSK’s ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire’s proposed labeling for Transpire’s Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire’s Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 2 of the ’242 patent, and thus directly infringes claim 2 of the ’242 patent, either literally or under the doctrine of equivalents.

137. On information and belief, Transpire’s Proposed ANDA Product comprises the medical dispenser of claim 2, wherein said plurality of said medicament carriers consists of a first and a second medicament carrier, each of said medicament carriers carrying distinct medicament portions in powder form, each of said medicament dose portions of said first medicament carrier comprising a bronchodilator as the active medicament component and each of said medicament dose portions of said second medicament carrier comprising an anti-inflammatory as the active medicament component. Further, on information and belief, Transpire’s Proposed ANDA Product comprises a bronchodilator, vilanterol trifenatate, as the active medicament component, and an anti-inflammatory, fluticasone furoate, as the active medicament component. Accordingly, on information and belief, and subject to GSK’s ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire’s

proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 4 of the '242 patent, and thus directly infringe claim 4 of the '242 patent, either literally or under the doctrine of equivalents.

138. On information and belief, Transpire's Proposed ANDA Product comprises the medicament dispenser of claim 4, wherein said bronchodilator is a beta-agonist and said anti-inflammatory is a corticosteroid. On information and belief, Transpire's Proposed ANDA Product comprises vilanterol trifenatate, which is a beta-agonist, and fluticasone furoate, which is a corticosteroid. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 5 of the '242 patent, and thus directly infringe claim 5 of the '242 patent, either literally or under the doctrine of equivalents.

139. On information and belief, if the FDA were to approve the Transpire ANDA, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product, including administration of Transpire's Proposed ANDA Product according to the label instructions, would cause patients, physicians, prescribers, and/or other healthcare providers to directly infringe at least claims 1-2 and 4-5 of the '242 patent. Transpire would actively induce and contribute to such direct infringement.

140. On information and belief, Transpire markets the Transpire Inhaler Product for co-development partnerships in which a pharmaceutical partner uses the Transpire Inhaler Product for an existing therapeutic. Ex. O. On information and belief, Transpire also markets the Transpire Inhaler Product for "strategic partnerships and licensing agreements to bring Transpire Bio's early-stage and mid-stage therapeutic assets to market." *Id.* Finally, on information and belief, Transpire markets the Transpire Inhaler Product for commercialization partnerships for the commercialization of "Transpire Bio's early-entry, difficult-to-replicate asthma/COPD generic inhaled therapies." *Id.*

141. Accordingly, on information and belief, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Transpire Inhaler Product would cause its customers and co-development and commercialization partners to directly infringe at least claims 1-2 of the '242 patent. Transpire would actively induce and contribute to such direct infringement.

142. Transpire has knowledge of the claims of the '242 patent as evidenced at least by Transpire's Paragraph IV Notice Letter. Despite this knowledge, Transpire has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing (including marketing Transpire's Proposed ANDA Product as a generic substitute for BREO ELLIPTA to be used and administered in the same manner as BREO ELLIPTA), distribution, and/or importation of Transpire's Proposed ANDA Product with the proposed labeling to be included for the Proposed ANDA Product, immediately and imminently upon approval of ANDA No. 218914. Despite knowledge of the '242 patent, Transpire has also engaged in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Transpire Inhaler Product. On

information and belief, and subject to GSK's ongoing investigation and discovery efforts, by engaging in the forgoing activities, Transpire specifically intends to infringe the '242 patent.

143. On information and belief, Transpire's specific intent to actively induce and/or contribute to infringement of at least claims 1-2 and 4-5 of the '242 patent includes Transpire's decision to proceed with its plan to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product, despite being aware that the proposed labeling to be included for the Proposed ANDA Product instructs, directs, recommends, encourages, and/or promotes direct infringement of the '242 patent.

144. Further, on information and belief, Transpire's specific intent to actively induce and/or contribute to the infringement of at least claims 1-2 of the '242 patent includes the representations on Transpire's website offering to sell, market, and/or distribute the Transpire Inhaler Product to its customers and co-development and commercialization partners.

145. On information and belief, and with full knowledge of the '242 patent, Transpire intends to and will actively induce infringement of the '242 patent when Transpire's Proposed ANDA is approved and will do so immediately and imminently upon approval.

146. On information and belief, and with full knowledge of the '242 patent, Transpire intends to and has actively induced infringement of the '242 patent by offering the Transpire Inhaler Product to its customers and co-development and commercialization partners.

147. BREO ELLIPTA and any corresponding generic fluticasone furoate and vilanterol trifenatate inhalation powder product is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1-2 and 4-5 of the '242 patent. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, Transpire, with full knowledge of the '242 patent, knows that its Proposed ANDA Product is especially adapted for

use in a manner that infringes the ’242 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1-2 and 4-5 of the ’242 patent. Further, on information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire, with full knowledge of the ’242 patent, knows that the Transpire Inhaler Product is especially adapted for use in a manner that infringes the ’242 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1-2 of the ’281 patent.

148. Any launch by Transpire of the Proposed ANDA Product before expiration of the ’242 patent would cause GSK to suffer immediate and irreparable harm.

149. Unless Transpire is enjoined from infringing the ’242 patent, actively inducing infringement of the ’242 patent, and contributing to the infringement of others of the ’242 patent, GSK will suffer irreparable injury. GSK has no adequate remedy at law.

150. Transpire’s infringement of the ’242 patent is willful.

COUNT IV
DECLARATORY JUDGMENT OF
INFRINGEMENT OF THE ’242 PATENT

151. GSK incorporates Paragraphs 1 through 47 and 57 through 69 as if fully set forth herein.

152. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

153. On information and belief, Transpire submitted the Transpire ANDA to obtain FDA approval to market its Proposed ANDA Product prior to expiration of the ’242 patent and is making preparations to launch, market, and sell the Proposed ANDA Product upon FDA approval. In addition, as evidenced on its website, Transpire is currently, or imminently will be, marketing and selling the Transpire Inhaler Product prior to expiration of the ’242 patent. These

actions create an actual, immediate, and real controversy within the Declaratory Judgment Act that Transpire has directly or indirectly infringed or will directly or indirectly infringe at least one claim of each of the asserted patents by engaging in the commercial manufacture, use, offer to sell, sale or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product, or by actively inducing or contributing to that infringement of at least one claim of the '242 patent prior to its expiration.

154. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product and/or the Transpire Inhaler Product by Transpire before the expiration of the '242 patent would constitute infringement by Transpire of the '242 patent under 35 U.S.C. §§ 271(a)-(c).

155. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, if Transpire's Proposed ANDA Product is approved, Transpire will make, use, offer for sale, sell, market, distribute, and/or import Transpire's Proposed ANDA Product, comprising a medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions, and would infringe at least, by way of example, claims 1-2, and 4-5 of the '242 patent.

156. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, Transpire's preparations for making, offering for sale, selling, marketing, distributing, and/or importing the Transpire Inhaler Product, comprising a medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions, and infringes at least, by way of example, claims 1-2 of the '242 patent.

157. Claims 1-2 and 4-5 of the '242 patent recite as follows:

> 1. A medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions, said medicament dispenser comprising
>
> > (a) a dispensing mechanism actuable for dispensing the distinct medicament portions carried by said at least one medicament carrier;
> >
> > (b) a mouthpiece; and
> >
> > (c) a cover for said mouthpiece, said cover being movably mounted to the dispenser for sequential movement from a first position, in which said mouthpiece is covered, to a second position, in which said mouthpiece is part-uncovered, to a third position in which said mouthpiece is uncovered;
> >
> > wherein said cover is adapted to couple with said dispensing mechanism such that movement of the cover from the first position to the second position does not result in actuation of the dispensing mechanism, but any further movement of the cover from the second position to the third position results in actuation of the dispensing mechanism.
>
> 2. A medicament dispenser according to claim 1 including a plurality of said medicament carriers each carrying multiple distinct medicament dose portions.
>
> 4. A medicament dispenser according to claim 2, wherein said plurality of said medicament carriers consists of a first and a second medicament carrier, each of said medicament carriers carrying distinct medicament portions in powder form, each of said medicament dose portions of said first medicament carrier comprising a bronchodilator as the active medicament component and each of said medicament dose portions of said second medicament carrier comprising an anti-inflammatory as the active medicament component.
>
> 5. A medicament dispenser according to claim 4, wherein said bronchodilator is a beta-agonist and said anti-inflammatory is a corticosteroid.

158. On information and belief, Transpire's Proposed ANDA Product, will have the same route of administration and dosage form as BREO ELLIPTA, which comprises an inhaler device. *See* 21 C.F.R. § 314.94(a)(6). Accordingly, on information and belief, Transpire's Proposed ANDA Product will comprise an inhaler device.

159. Additionally, on information and belief, Transpire's Proposed ANDA Product will have the same active ingredients as BREO ELLIPTA and will substantively copy the BREO ELLIPTA Label with respect to the fluticasone furoate and vilanterol inhalation powder, 100 mcg/25 mcg strength. *See* 21 C.F.R. §§ 314.94(a)(5), (a)(8)(iii)-(iv). Accordingly, on information and belief, Transpire's Proposed ANDA Product will contain as dry powder active ingredients: (1) fluticasone furoate, which is a bronchodilator, and more specifically a beta-agonist; and (2) vilanterol trifenatate, which is an anti-inflammatory, and more specifically a corticosteroid.

160. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions. *See, e.g.*, Ex. K ("We have developed commercial scale, clinical-stage inhalation formulation technologies and delivery platforms that are fully customizable to different clinical applications."); *id.* ("Our inhalation technology platforms have wide applicability and can support small molecules, polypeptides, protein, oligonucleotides, biologics, and vaccines."); *id.* (Rollingstar inhalation device pictured).

161. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser, which comprises a dispensing mechanism actuable for dispensing the distinct medicament portions carried by said at least one medicament carrier. Exs. K, N (demonstrating use of Transpire's Rollingstar dry powder inhaler).

162. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser which comprises a mouthpiece. Ex. K (Rollingstar inhaler mouthpiece).

163. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser which comprises a cover for said mouthpiece, said cover being movably mounted to the dispenser for sequential movement from a first position, in which said mouthpiece is covered, to a second position, in which said mouthpiece is part-uncovered, to a third position in which said mouthpiece is uncovered. Ex. K (Rollingstar inhaler in closed position, with mouthpiece covered); *id.* (Rollingstar inhaler mouthpiece uncovered when in use).

164. On information and belief, the cover of Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser which is adapted to couple with said dispensing mechanism such that movement of the cover from the first position to the second position does not result in actuation of the dispensing mechanism, but any further movement of the cover from the second position to the third position results in actuation of the dispensing mechanism. Ex. K (Rollingstar inhaler in closed position, with mouthpiece covered); *id.* (Rollingstar inhaler mouthpiece uncovered when in use).

165. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 1 of the '242 patent, and thus directly infringes claim 1 of the '242 patent, either literally or under the doctrine of equivalents.

166. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise the medicament dispenser of claim 1, and includes a plurality of said

medicament carriers each carrying multiple distinct medicament dose portions. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 2 of the '242 patent, and thus directly infringes claim 2 of the '242 patent, either literally or under the doctrine of equivalents.

167. On information and belief, Transpire's Proposed ANDA Product comprises the medical dispenser of claim 2, wherein said plurality of said medicament carriers consists of a first and a second medicament carrier, each of said medicament carriers carrying distinct medicament portions in powder form, each of said medicament dose portions of said first medicament carrier comprising a bronchodilator as the active medicament component and each of said medicament dose portions of said second medicament carrier comprising an anti-inflammatory as the active medicament component. Further, on information and belief, Transpire's Proposed ANDA Product comprises a bronchodilator, vilanterol trifenatate, as the active medicament component, and an anti-inflammatory, fluticasone furoate, as the active medicament component. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 4 of the '242 patent, and thus directly infringe claim 4 of the '242 patent, either literally or under the doctrine of equivalents.

168. On information and belief, Transpire's Proposed ANDA Product comprises the medicament dispenser of claim 4, wherein said bronchodilator is a beta-agonist and said anti-inflammatory is a corticosteroid. On information and belief, Transpire's Proposed ANDA Product comprises vilanterol trifenatate, which is a beta-agonist, and fluticasone furoate, which is a corticosteroid. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 5 of the '242 patent, and thus directly infringe claim 5 of the '242 patent, either literally or under the doctrine of equivalents.

169. On information and belief, if the FDA were to approve the Transpire ANDA, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product, including administration of Transpire's Proposed ANDA Product according to the label instructions, would cause patients, physicians, prescribers, and/or other healthcare providers to directly infringe at least claims 1-2 and 4-5 of the '242 patent. Transpire would actively induce and contribute to such direct infringement.

170. On information and belief, Transpire markets the Transpire Inhaler Product for co-development partnerships in which a pharmaceutical partner uses the Transpire Inhaler Product for an existing therapeutic. Ex. O. On information and belief, Transpire also markets the Transpire Inhaler Product for "strategic partnerships and licensing agreements to bring Transpire Bio's early-stage and mid-stage therapeutic assets to market." *Id.* Finally, on information and

belief, Transpire markets the Transpire Inhaler Product for commercialization partnerships for the commercialization of "Transpire Bio's early-entry, difficult-to-replicate asthma/COPD generic inhaled therapies." *Id.*

171. Accordingly, on information and belief, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Transpire Inhaler Product would cause its customers and co-development and commercialization partners to directly infringe at least claims 1-2 of the '242 patent. Transpire would actively induce and contribute to such direct infringement.

172. Transpire has knowledge of the claims of the '242 patent as evidenced at least by Transpire's Paragraph IV Notice Letter. Despite this knowledge, Transpire has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing (including marketing Transpire's Proposed ANDA Product as a generic substitute for BREO ELLIPTA to be used and administered in the same manner as BREO ELLIPTA), distribution, and/or importation of Transpire's Proposed ANDA Product with the proposed labeling to be included for the Proposed ANDA Product, immediately and imminently upon approval of ANDA No. 218914. Despite knowledge of the '242 patent, Transpire has also engaged in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Transpire Inhaler Product. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, by engaging in the forgoing activities, Transpire specifically intends to infringe the '242 patent.

173. On information and belief, Transpire's specific intent to actively induce and/or contribute to infringement of at least claims 1-2 and 4-5 of the '242 patent includes Transpire's decision to proceed with its plan to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product, despite

being aware that the proposed labeling to be included for the Proposed ANDA Product instructs, directs, recommends, encourages, and/or promotes direct infringement of the ’242 patent.

174. Further, on information and belief, Transpire’s specific intent to actively induce and/or contribute to the infringement of at least claims 1-2 of the ’242 patent includes the representations on Transpire’s website offering to sell, market, and/or distribute the Transpire Inhaler Product to its customers and co-development and commercialization partners.

175. On information and belief, and with full knowledge of the ’242 patent, Transpire intends to and will actively induce infringement of the ’242 patent when Transpire’s Proposed ANDA is approved and will do so immediately and imminently upon approval.

176. On information and belief, and with full knowledge of the ’242 patent, Transpire intends to and has actively induced infringement of the ’242 patent by offering the Transpire Inhaler Product to its customers and co-development and commercialization partners.

177. BREO ELLIPTA and any corresponding generic fluticasone furoate and vilanterol trifenatate inhalation powder product is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1-2 and 4-5 of the ’242 patent. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire, with full knowledge of the ’242 patent, knows that its Proposed ANDA Product is especially adapted for use in a manner that infringes the ’242 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1-2 and 4-5 of the ’242 patent. Further, on information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire, with full knowledge of the ’242 patent, knows that the Transpire Inhaler Product is especially adapted for use in a manner that infringes the ’242 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1-2 of the ’281 patent.

178. Any launch by Transpire of the Proposed ANDA Product or the Transpire Inhaler Product before expiration of the ’242 patent would cause GSK to suffer immediate and irreparable harm.

179. Unless Transpire is enjoined from infringing the ’242 patent, actively inducing infringement of the ’242 patent, and contributing to the infringement of others of the ’242 patent, GSK will suffer irreparable injury. GSK has no adequate remedy at law.

180. Transpire’s infringement of the ’242 patent would be willful.

181. For at least the above reasons, a definite and concrete controversy exists between GSK and Transpire as to whether Transpire’s commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product or Transpire Inhaler Product prior to the expiration of the ’242 patent would infringe the ’242 patent. Accordingly, GSK is entitled to a declaratory judgment that it would.

COUNT V
INFRINGEMENT OF THE ’281 PATENT

182. GSK incorporates Paragraphs 1 through 47 and 57 through 69 as if fully set forth herein.

183. The submission of the Transpire ANDA to the FDA, including the Paragraph IV Certification submitted therewith, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Proposed ANDA Product prior to the expiration of the ’281 patent, constitutes infringement by Transpire of the ’281 patent under 35 U.S.C. § 271(e)(2)(A).

184. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product and/or the Transpire

Inhaler Product by Transpire before the expiration of the ’281 patent would constitute infringement by Transpire of the ’281 patent under 35 U.S.C. §§ 271(a)-(c).

185. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, if Transpire’s Proposed ANDA Product is approved, Transpire will make, use, offer for sale, sell, market, distribute, and/or import Transpire’s Proposed ANDA Product, comprising a manifold for use in a medicament dispenser, and would infringe at least, by way of example, claims 1, 32, 39, and 44 of the ’281 patent.

186. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire makes, offers for sale, sells, markets, distributes, and/or imports the Transpire Inhaler Product, comprising a manifold for use in a medicament dispenser, and would infringe at least, by way of example, claims 1, 32, and 39 of the ’281 patent.

187. Claims 1, 32, 39, and 44 of the ’281 patent recite as follows:

> 1. A manifold for use in a medicament dispenser device for the delivery of medicament powder from an open blister pocket of each of plural blister packs, the manifold comprising
>
> a body,
>
> said body defining a chimney having only a single chimney inlet and plural chimney exits for directing airflow from said chimney inlet to said chimney exits;
>
> the body further defining a chamber having plural chamber inlets and a chamber exit,
>
> wherein the chimney exits and chamber inlets are arranged to form plural pairings of chimney exit and chamber inlet, each said pairing in use associated with an open blister pocket of a different one of said plural blister packs;
>
> wherein the chimney exit and chamber inlet of the plural pairings lie side-by-side each other such that when said open blister pocket of the associated blister packs are positioned adjacent thereto said airflow is directed from chimney exit to chamber inlet via the

> associated open blister pockets to entrain said medicament powder and enable transport thereof in the airflow from the chamber inlet to said chamber exit, and wherein one or more bleed holes are provided between the chimney and the chamber such that bleed airflow is able to be directed into the chamber to disruptively impact the airflow that transports the entrained medicament powder.
>
> 32. A medicament dispenser device, comprising a manifold according to claim 1, the medicament dispenser device suitable for the delivery of medicament powder from at least one blister pack having at least one blister pocket.
>
> 39. The medicament dispenser device according to claim 32 comprising at least one blister pack containing medicament in powder form.
>
> 44. The medicament dispenser device according to claim 39, comprising first and second blister packs, wherein the medicament powder contained in said first blister pack comprises a bronchodilator as the active medicament component and the medicament powder contained in said second blister pack comprises an anti-inflammatory as the active medicament component.

188. On information and belief, Transpire's Proposed ANDA Product, will have the same route of administration and dosage form as BREO ELLIPTA, which comprises an inhaler device. *See* 21 C.F.R. § 314.94(a)(6). Accordingly, on information and belief, Transpire's Proposed ANDA Product will comprise an inhaler device.

189. Additionally, on information and belief, Transpire's Proposed ANDA Product will have the same active ingredients as BREO ELLIPTA and will substantively copy the BREO ELLIPTA Label with respect to the fluticasone furoate and vilanterol inhalation powder, 100 mcg/25 mcg strength. *See* 21 C.F.R. §§ 314.94(a)(5), (a)(8)(iii)-(iv). Accordingly, on information and belief, Transpire's Proposed ANDA Product will contain as dry powder active ingredients: (1) fluticasone furoate, which is a bronchodilator, and more specifically a beta-agonist; and (2) vilanterol trifenatate, which is an anti-inflammatory, and more specifically a corticosteroid.

190. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold for use in a medicament dispenser device for the delivery of medicament powder from an open blister pocket of each of plural blister packs. Ex. K (showing Transpire's manufacture of medicament blister packs).

191. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold which further comprises a body.

192. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold, in which the body of the manifold defines a chimney having only a single chimney inlet and plural chimney exits for directing airflow from the chimney inlet to the chimney exists.

193. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold, in which the body of the manifold further defines a chamber having plural chamber inlets and a chamber exit.

194. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprises a manifold, in which the chimney exits and chamber inlets are arranged to form plural pairings of chimney exit and chamber inlet, each said pairing in use associated with an open blister pocket of a different one of said plural blister packs.

195. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold, in which the chimney exit and chamber inlet of the plural pairings lie side-by-side each other such that when said open blister pocket of the associated blister packs are positioned adjacent thereto said airflow is directed from chimney exit to chamber inlet via the associated open blister pockets to entrain said medicament powder and enable transport thereof in the airflow from the chamber inlet to said chamber exit, and wherein

one or more bleed holes are provided between the chimney and the chamber such that bleed airflow is able to be directed into the chamber to disruptively impact the airflow that transports the entrained medicament powder.

196. Accordingly, on information and belief and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of the manifold for use in a medicament dispenser device recited in at least claim 1 of the '281 patent, and thus directly infringe claim 1 of the '281 patent, either literally or under the doctrine of equivalents.

197. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser device, comprising a manifold according to claim 1, the medicament dispenser device suitable for the delivery of medicament powder from at least one blister pack having at least one blister pocket. *See, e.g.*, Ex. K ("We have developed commercial scale, clinical-stage inhalation formulation technologies and delivery platforms that are fully customizable to different clinical applications."); *id.* ("Our inhalation technology platforms have wide applicability and can support small molecules, polypeptides, protein, oligonucleotides, biologics, and vaccines."); *id.* (Rollingstar inhalation device pictured); *id.* (showing Transpire's manufacture of medicament blister packs). Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of

the manifold for use in a medicament dispenser device recited in at least claim 32 of the ’281 patent, and thus directly infringe claim 32 of the ’281 patent, either literally or under the doctrine of equivalents.

198. On information and belief, Transpire’s Proposed ANDA Product and the Transpire Inhaler Product comprise the medicament dispenser device of claim 32 comprising at least one blister pack containing medicament in powder form. Ex. K (showing Transpire’s manufacture of medicament blister packs). Accordingly, on information and belief and subject to GSK’s ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire’s proposed labeling for Transpire’s Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire’s Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of the manifold for use in a medicament dispenser device recited in at least claim 39 of the ’281 patent, and thus directly infringe claim 39 of the ’281 patent, either literally or under the doctrine of equivalents.

199. On information and belief, Transpire’s Proposed ANDA Product comprises a medicament dispenser device of claim 39, comprising first and second blister packs, wherein the medicament powder contained in said first blister pack comprises a bronchodilator as the active medicament component and the medicament powder contained in said second blister pack comprises an anti-inflammatory as the active medicament component. On information and belief, Transpire’s Proposed ANDA Product comprises a bronchodilator, vilanterol trifenatate, as the active medicament component, and an anti-inflammatory, fluticasone furoate, as the active medicament component. Accordingly, on information and belief and subject to GSK’s ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire’s proposed labeling for Transpire’s Proposed ANDA Product), offer for sale, sale, marketing,

distribution, and/or importation of Transpire's Proposed ANDA Product will satisfy each of the recited elements of the manifold for use in a medicament dispenser device recited in at least claim 44 of the '281 patent, and thus directly infringe claim 44 of the '281 patent, either literally or under the doctrine of equivalents.

200. On information and belief, if the FDA were to approve the Transpire ANDA, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product, including administration of Transpire's Proposed ANDA Product according to the label instructions, would cause patients, physicians, prescribers, and/or other healthcare providers to directly infringe at least claims 1, 32, 39, and 44 of the '281 patent. Transpire would actively induce and contribute to such direct infringement.

201. On information and belief, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Transpire Inhaler Product would cause its customers and co-development and commercialization partners to directly infringe at least claims 1, 32, and 39 of the '281 patent. Transpire would actively induce and contribute to such direct infringement.

202. Transpire has knowledge of the claims of the '281 patent as evidenced at least by Transpire's Paragraph IV Notice Letter. Despite this knowledge, Transpire has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing (including marketing Transpire's Proposed ANDA Product as a generic substitute for BREO ELLIPTA to be used and administered in the same manner as BREO ELLIPTA), distribution, and/or importation of Transpire's Proposed ANDA Product with the proposed labeling to be included for the Proposed ANDA Product, immediately and imminently upon approval of ANDA No. 218914.

Despite this knowledge, Transpire has also engaged in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Transpire Inhaler Product. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, by engaging in the forgoing activities, Transpire specifically intends to infringe the '281 patent.

203. On information and belief, Transpire's specific intent to actively induce and/or contribute to infringement of at least claims 1, 32, 39, and 44 of the '281 patent includes Transpire's decision to proceed with its plan to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product, despite being aware that the proposed labeling to be included for the Proposed ANDA Product instructs, directs, recommends, encourages, and/or promotes direct infringement of the '281 patent.

204. On information and belief, Transpire markets the Transpire Inhaler Product for co-development partnerships in which a pharmaceutical partner uses the Transpire Inhaler Product for an existing therapeutic. Ex. O. On information and belief, Transpire also markets the Transpire Inhaler Product for "strategic partnerships and licensing agreements to bring Transpire Bio's early-stage and mid-stage therapeutic assets to market." *Id.* Finally, on information and belief, Transpire markets the Transpire Inhaler Product for commercialization partnerships for the commercialization of "Transpire Bio's early-entry, difficult-to-replicate asthma/COPD generic inhaled therapies." *Id.*

205. Accordingly, on information and belief, Transpire's specific intent to actively induce and/or contribute to the infringement of at least claims 1, 32, and 39 of the '281 patent includes the representations on Transpire's website offering to sell, market, and/or distribute the Transpire Inhaler Product to its customers and co-development and commercialization partners.

206. On information and belief, and with full knowledge of the ’281 patent, Transpire intends to and will actively induce infringement of the ’281 patent when Transpire’s Proposed ANDA is approved and will do so immediately and imminently upon approval.

207. On information and belief, and with full knowledge of the ’281 patent, Transpire intends to and has actively induced infringement of the ’281 patent by offering to sell, market, and/or distribute the Transpire Inhaler Product to its customers and co-development and commercialization partners.

208. BREO ELLIPTA and any corresponding generic fluticasone furoate and vilanterol trifenatate inhalation powder product is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1, 32, 39, and 44 of the ’281 patent. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire, with full knowledge of the ’281 patent, knows that its Proposed ANDA Product is especially adapted for use in a manner that infringes the ’281 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1, 32, 39, and 44 of the ’281 patent. Further, on information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire, with full knowledge of the ’281 patent, knows that the Transpire Inhaler Product is especially adapted for use in a manner that infringes the ’281 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1, 32, 39 of the ’281 patent.

209. Any launch by Transpire of the Proposed ANDA Product before expiration of the ’281 patent would cause GSK to suffer immediate and irreparable harm.

210. Unless Transpire is enjoined from infringing the ’281 patent, actively inducing infringement of the ’281 patent, and contributing to the infringement of others of the ’281 patent, GSK will suffer irreparable injury. GSK has no adequate remedy at law.

211. Transpire’s infringement of the ’281 patent is willful.

COUNT VI
DECLARATORY JUDGMENT OF
INFRINGEMENT OF THE ’281 PATENT

212. GSK incorporates Paragraphs 1 through 47 and 57 through 69 as if fully set forth herein.

213. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

214. On information and belief, Transpire submitted the Transpire ANDA to obtain FDA approval to market its Proposed ANDA Product and is making preparations to launch, market, and sell the Proposed ANDA Product upon FDA approval. In addition, as evidenced on its website, Transpire is currently, or imminently will be, marketing and selling the Transpire Inhaler Product. These actions create an actual, immediate, and real controversy within the Declaratory Judgment Act that Transpire has directly or indirectly infringed or will directly or indirectly infringe at least one claim of each of the asserted patents by engaging in the commercial manufacture, use, offer to sell, sale or importation of Transpire’s Proposed ANDA Product and/or the Transpire Inhaler Product, or by actively inducing or contributing to that infringement of at least one claim of the ’281 patent prior to its expiration.

215. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product and/or the Transpire

Inhaler Product by Transpire before the expiration of the ’281 patent would constitute infringement by Transpire of the ’281 patent under 35 U.S.C. §§ 271(a)-(c).

216. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, if Transpire’s Proposed ANDA Product is approved, Transpire will make, use, offer for sale, sell, market, distribute, and/or import Transpire’s Proposed ANDA Product, comprising a manifold for use in a medicament dispenser, and would infringe at least, by way of example, claims 1, 32, 39, and 44 of the ’281 patent.

217. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire’s preparations for making, offering for sale, selling, marketing, distributing, and/or importing the Transpire Inhaler Product, comprise a manifold for use in a medicament dispenser, and would infringe at least, by way of example, claims 1, 32, and 39 of the ’281 patent.

218. Claims 1, 32, 39, and 44 of the ’281 patent recite as follows:

> 1. A manifold for use in a medicament dispenser device for the delivery of medicament powder from an open blister pocket of each of plural blister packs, the manifold comprising
>
> a body,
>
> said body defining a chimney having only a single chimney inlet and plural chimney exits for directing airflow from said chimney inlet to said chimney exits;
>
> the body further defining a chamber having plural chamber inlets and a chamber exit,
>
> wherein the chimney exits and chamber inlets are arranged to form plural pairings of chimney exit and chamber inlet, each said pairing in use associated with an open blister pocket of a different one of said plural blister packs;
>
> wherein the chimney exit and chamber inlet of the plural pairings lie side-by-side each other such that when said open blister pocket of

> the associated blister packs are positioned adjacent thereto said airflow is directed from chimney exit to chamber inlet via the associated open blister pockets to entrain said medicament powder and enable transport thereof in the airflow from the chamber inlet to said chamber exit, and wherein one or more bleed holes are provided between the chimney and the chamber such that bleed airflow is able to be directed into the chamber to disruptively impact the airflow that transports the entrained medicament powder.
>
> 32. A medicament dispenser device, comprising a manifold according to claim 1, the medicament dispenser device suitable for the delivery of medicament powder from at least one blister pack having at least one blister pocket.
>
> 39. The medicament dispenser device according to claim 32 comprising at least one blister pack containing medicament in powder form.
>
> 44. The medicament dispenser device according to claim 39, comprising first and second blister packs, wherein the medicament powder contained in said first blister pack comprises a bronchodilator as the active medicament component and the medicament powder contained in said second blister pack comprises an anti-inflammatory as the active medicament component.

219. On information and belief, Transpire's Proposed ANDA Product will have the same route of administration and dosage form as BREO ELLIPTA, which comprises an inhaler device. *See* 21 C.F.R. § 314.94(a)(6). Accordingly, on information and belief, Transpire's Proposed ANDA Product will comprise an inhaler device.

220. Additionally, on information and belief, Transpire's Proposed ANDA Product will have the same active ingredients as BREO ELLIPTA and will substantively copy the BREO ELLIPTA Label with respect to the fluticasone furoate and vilanterol inhalation powder, 100 mcg/25 mcg strength. *See* 21 C.F.R. §§ 314.94(a)(5), (a)(8)(iii)-(iv). Accordingly, on information and belief, Transpire's Proposed ANDA Product will contain as dry powder active ingredients: (1) fluticasone furoate, which is a bronchodilator, and more specifically a beta-

agonist; and (2) vilanterol trifenatate, which is an anti-inflammatory, and more specifically a corticosteroid.

221. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold for use in a medicament dispenser device for the delivery of medicament powder from an open blister pocket of each of plural blister packs. Ex. K (showing Transpire's manufacture of medicament blister packs).

222. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold which further comprises a body.

223. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold, in which the body of the manifold defines a chimney having only a single chimney inlet and plural chimney exits for directing airflow from the chimney inlet to the chimney exists.

224. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold, in which the body of the manifold further defines a chamber having plural chamber inlets and a chamber exit.

225. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprises a manifold, in which the chimney exits and chamber inlets are arranged to form plural pairings of chimney exit and chamber inlet, each said pairing in use associated with an open blister pocket of a different one of said plural blister packs.

226. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a manifold, in which the chimney exit and chamber inlet of the plural pairings lie side-by-side each other such that when said open blister pocket of the associated blister packs are positioned adjacent thereto said airflow is directed from chimney exit to

chamber inlet via the associated open blister pockets to entrain said medicament powder and enable transport thereof in the airflow from the chamber inlet to said chamber exit, and wherein one or more bleed holes are provided between the chimney and the chamber such that bleed airflow is able to be directed into the chamber to disruptively impact the airflow that transports the entrained medicament powder.

227. Accordingly, on information and belief and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of the manifold for use in a medicament dispenser device recited in at least claim 1 of the '281 patent, and thus directly infringe claim 1 of the '281 patent, either literally or under the doctrine of equivalents.

228. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser device, comprising a manifold according to claim 1, the medicament dispenser device suitable for the delivery of medicament powder from at least one blister pack having at least one blister pocket. *See, e.g.*, Ex. K ("We have developed commercial scale, clinical-stage inhalation formulation technologies and delivery platforms that are fully customizable to different clinical applications."); *id.* ("Our inhalation technology platforms have wide applicability and can support small molecules, polypeptides, protein, oligonucleotides, biologics, and vaccines."); *id.* (Rollingstar inhalation device pictured); *id.* (showing Transpire's manufacture of medicament blister packs). Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA

Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of the manifold for use in a medicament dispenser device recited in at least claim 32 of the '281 patent, and thus directly infringe claim 32 of the '281 patent, either literally or under the doctrine of equivalents.

229. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise the medicament dispenser device of claim 32 comprising at least one blister pack containing medicament in powder form. Ex. K (showing Transpire's manufacture of medicament blister packs). Accordingly, on information and belief and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of the manifold for use in a medicament dispenser device recited in at least claim 39 of the '281 patent, and thus directly infringe claim 39 of the '281 patent, either literally or under the doctrine of equivalents.

230. On information and belief, Transpire's Proposed ANDA Product comprises a medicament dispenser device of claim 39, comprising first and second blister packs, wherein the medicament powder contained in said first blister pack comprises a bronchodilator as the active medicament component and the medicament powder contained in said second blister pack comprises an anti-inflammatory as the active medicament component. On information and belief, Transpire's Proposed ANDA Product comprises a bronchodilator, vilanterol trifenatate, as the active medicament component, and an anti-inflammatory, fluticasone furoate, as the active medicament component. Accordingly, on information and belief and subject to GSK's ongoing

investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product will satisfy each of the recited elements of the manifold for use in a medicament dispenser device recited in at least claim 44 of the '281 patent, and thus directly infringe claim 44 of the '281 patent, either literally or under the doctrine of equivalents.

231. On information and belief, if the FDA were to approve the Transpire ANDA, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product, including administration of Transpire's Proposed ANDA Product according to the label instructions, would cause patients, physicians, prescribers, and/or other healthcare providers to directly infringe at least claims 1, 32, 39, and 44 of the '281 patent. Transpire would actively induce and contribute to such direct infringement.

232. On information and belief, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Transpire Inhaler Product would cause its customers and co-development and commercialization partners to directly infringe at least claims 1, 32, and 39 of the '281 patent. Transpire would actively induce and contribute to such direct infringement.

233. Transpire has knowledge of the claims of the '281 patent as evidenced at least by Transpire's Paragraph IV Notice Letter. Despite this knowledge, Transpire has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing (including marketing Transpire's Proposed ANDA Product as a generic substitute for BREO ELLIPTA to be used and administered in the same manner as BREO ELLIPTA), distribution, and/or importation

of Transpire's Proposed ANDA Product with the proposed labeling to be included for the Proposed ANDA Product, immediately and imminently upon approval of ANDA No. 218914. Despite this knowledge, Transpire has also engaged in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Transpire Inhaler Product. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, by engaging in the forgoing activities, Transpire specifically intends to infringe the '281 patent.

234. On information and belief, Transpire's specific intent to actively induce and/or contribute to infringement of at least claims 1, 32, 39, and 44 of the '281 patent includes Transpire's decision to proceed with its plan to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product, despite being aware that the proposed labeling to be included for the Proposed ANDA Product instructs, directs, recommends, encourages, and/or promotes direct infringement of the '281 patent.

235. On information and belief, Transpire markets the Transpire Inhaler Product for co-development partnerships in which a pharmaceutical partner uses the Transpire Inhaler Product for an existing therapeutic. Ex. O. On information and belief, Transpire also markets the Transpire Inhaler Product for "strategic partnerships and licensing agreements to bring Transpire Bio's early-stage and mid-stage therapeutic assets to market." *Id.* Finally, on information and belief, Transpire markets the Transpire Inhaler Product for commercialization partnerships for the commercialization of "Transpire Bio's early-entry, difficult-to-replicate asthma/COPD generic inhaled therapies." *Id.*

236. Accordingly, on information and belief, Transpire's specific intent to actively induce and/or contribute to the infringement of at least claims 1, 32, and 39 of the '281 patent

includes the representations on Transpire's website offering to sell, market, and/or distribute the Transpire Inhaler Product to its customers and co-development and commercialization partners.

237. On information and belief, and with full knowledge of the '281 patent, Transpire intends to and will actively induce infringement of the '281 patent when Transpire's Proposed ANDA is approved and will do so immediately and imminently upon approval.

238. On information and belief, and with full knowledge of the '281 patent, Transpire intends to and has actively induced infringement of the '281 patent by offering to sell, market, and/or distribute the Transpire Inhaler Product to its customers and co-development and commercialization partners.

239. BREO ELLIPTA and any corresponding generic fluticasone furoate and vilanterol trifenatate inhalation powder product is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1, 32, 39, and 44 of the '281 patent. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, Transpire, with full knowledge of the '281 patent, knows that its Proposed ANDA Product is especially adapted for use in a manner that infringes the '281 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1, 32, 39, and 44 of the '281 patent. Further, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, Transpire, with full knowledge of the '281 patent, knows that the Transpire Inhaler Product is especially adapted for use in a manner that infringes the '281 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1, 32, 39 of the '281 patent.

240. Any launch by Transpire of the Proposed ANDA Product or Transpire Inhaler Products before expiration of the ’281 patent would cause GSK to suffer immediate and irreparable harm.

241. Unless Transpire is enjoined from infringing the ’281 patent, actively inducing infringement of the ’281 patent, and contributing to the infringement of others of the ’281 patent, GSK will suffer irreparable injury. GSK has no adequate remedy at law.

242. Transpire’s infringement of the ’281 patent would be willful.

243. For at least the above reasons, a definite and concrete controversy exists between GSK and Transpire as to whether Transpire’s commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product or Transpire Inhaler Product prior to the expiration of the ’281 patent would infringe the ’281 patent. GSK is entitled to a declaratory judgment that it would.

COUNT VII
INFRINGEMENT OF THE ’968 PATENT

244. GSK incorporates Paragraphs 1 through 47 and 57 through 69 as if fully set forth herein.

245. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Transpire Inhaler Product by Transpire before the expiration of the ’968 patent would constitute infringement by Transpire of the ’968 patent under 35 U.S.C. §§ 271(a)-(c).

246. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire makes, offers for sale, sells, markets, distributes, and/or imports the Transpire Inhaler Product, comprising a medicament dispenser for use with at least one

medicament carrier carrying multiple distinct medicament portions, and would infringe at least, by way of example, claims 1 and 14 of the ’968 patent, which recite as follows:

> 1. A medicament dispenser for containing plural elongate form medicament carriers, each medicament carrier having multiple distinct medicament dose portions carried thereby, said dispenser having a housing, and within said housing a dispensing mechanism for dispensing the distinct medicament dose portions carried by each of said plural medicament carriers, said mechanism comprising,
>
> > a) at least one receiving station for receiving each of the plural medicament carriers;
> >
> > b) a release for releasing in combination a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said receiving station;
> >
> > c) an outlet, positioned to be in communication with the distinct medicament dose portions releasable by said release; and
> >
> > d) at least one indexer for individually indexing the distinct medicament dose portions of each of the plural medicament carriers, wherein said dispenser further comprises a movable cover for the outlet, wherein the cover:
> >
> > is movable from an at rest position, in which the cover covers the outlet, to a primed position and then an actuated position to uncover the outlet, and couples to the dispensing mechanism such that: movement of said cover from the primed position to the actuated position actuates one or more components of the dispensing mechanism, and movement of said cover from the at rest position to the primed position does not actuate said one or more components of the dispensing mechanism.
>
> 14. A medicament dispenser for containing plural elongate blister strip form medicament carriers, each medicament carrier having multiple distinct medicament dose portions carried in multiple distinct pockets which are spaced along the length of and defined between peelable base and lid sheets secured to each other, said dispenser having a housing, and within said housing a dispensing mechanism for dispensing the distinct medicament dose portions carried by each of said plural medicament carriers, said mechanism comprising,
>
> > at least one receiving station for receiving each of the plural medicament carriers;

> an opening station for receiving a pocket of each of said medicament carriers;
>
> a release for releasing in combination a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said receiving station, comprising:
>
> at least one peeler positioned to engage a base sheet and a lid sheet of a pocket which has been received in said opening station for peeling apart such a base sheet and lid sheet, to open such a pocket;
>
> a lid take-up spindle for each medicament carrier for winding up the lid sheet thereon;
>
> an outlet, positioned to be in communication with the distinct medicament dose portions releasable by said release and through which a user can access a medicament dose portion from an opened pocket; and
>
> an index wheel for each medicament carrier for individually indexing the distinct pockets of each of the plural medicament carriers;
>
> wherein said dispenser further comprises a movable cover that couples to the dispensing mechanism and that is movable from an at rest position, in which the cover covers the outlet, to a primed position and then an actuated position to uncover the outlet, and movement of the movable cover is coupled to the index wheels and lid take-up spindles by gearing that is arranged such that movement of the cover from the at rest position to the primed position does not result in any rotation of the index wheels and lid take-up spindles, but further movement of the cover to the actuated position results in sufficient rotation of the index wheels and lid take-up spindles to advance each medicament carrier by one pocket distance.

247. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser containing plural elongate form medicament carriers, each medicament carrier having multiple distinct medicament dose portions carried thereby, said dispenser having a housing, and within said housing a dispensing mechanism for dispensing the distinct medicament dose portions carried by each of said plural medicament carriers. Exs. K, N (demonstrating use of

Transpire's Rollingstar dry powder inhaler); Ex. K (showing Transpire's manufacture of medicament blister packs).

248. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising at least one receiving station for receiving each of the plural medicament carriers.

249. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a release for releasing in combination a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said receiving station.

250. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising an outlet, positioned to be in communication with the distinct medicament dose portions releasable by said release.

251. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising at least one indexer for individually indexing the distinct medicament dose portions of each of the plural medicament carriers, wherein said dispenser further comprises a movable cover for the outlet. Ex. K (showing cover that appears coupled to a dose indexer).

252. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a cover that is movable from an at rest position, in which the cover covers the outlet, to a primed position and then an actuated position to uncover the outlet, and couples to the dispensing mechanism such that: movement of said cover from the primed position to the actuated position actuates one or more components of the dispensing mechanism, and movement of said cover from the at rest position to the primed position does not actuate said one or more components of the dispensing mechanism. Ex. K (Rollingstar inhaler in closed position, with mouthpiece covered); *id.* (Rollingstar inhaler mouthpiece uncovered when in use).

253. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Transpire Inhaler Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 1 of the '968 patent, and thus directly infringe claim 1 of the '968 patent, either literally or under the doctrine of

254. Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser for containing plural elongate blister strip form medicament carriers, each medicament carrier having multiple distinct medicament dose portions carried in multiple distinct pockets which are spaced along the length of and defined between peelable base and lid sheets secured to each other, said dispenser having a housing, and within said housing a dispensing mechanism for dispensing the distinct medicament dose portions carried by each of said plural medicament carriers. Ex. K (showing Transpire's manufacture of medicament blister packs).

255. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a mechanism with at least one receiving station for receiving each of the plural medicament carriers.

256. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a mechanism with an opening station for receiving a pocket of each of said medicament carriers.

257. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a mechanism with a release for releasing in combination a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said receiving station.

258. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a receiving station with at least one peeler positioned to engage a base sheet and a lid sheet of a pocket which has been received in said opening station for peeling apart such a base sheet and lid sheet, to open such a pocket.

259. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a receiving station with a lid take-up spindle for each medicament carrier for winding up the lid sheet thereon.

260. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a receiving station with an outlet, positioned to be in communication with the distinct medicament dose portions releasable by said release and through which a user can access a medicament dose portion from an opened pocket.

261. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a receiving station with an index wheel for each medicament carrier for individually indexing the distinct pockets of each of the plural medicament carriers. Ex. K (showing cover that appears coupled to a dose indexer).

262. On information and belief, the Transpire Inhaler Product comprises a medicament dispenser comprising a dispenser which further comprises a movable cover that couples to the dispensing mechanism and that is movable from an at rest position, in which the cover covers the outlet, to a primed position and then an actuated position to uncover the outlet, and movement of the movable cover is coupled to the index wheels and lid take-up spindles by gearing that is arranged such that movement of the cover from the at rest position to the primed position does not result in any rotation of the index wheels and lid take-up spindles, but further movement of the cover to the actuated position results in sufficient rotation of the index wheels and lid take-up

spindles to advance each medicament carrier by one pocket distance. Ex. K (Rollingstar inhaler in closed position, with mouthpiece covered); *id.* (Rollingstar inhaler mouthpiece uncovered when in use).

263. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Transpire Inhaler Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 14 of the '968 patent, and thus directly infringe claim 14 of the '968 patent, either literally or under the doctrine of equivalents.

264. On information and belief, Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Transpire Inhaler Product would cause its customers and co-development and commercialization partners to directly infringe at least claims 1 and 14 of the '968 patent. Transpire would actively induce and contribute to such direct infringement.

265. On information and belief, Transpire has knowledge of the claims of the '968 patent at least by virtue of the '968 patent's prior listing in the Orange Book for BREO ELLIPTA. Despite this knowledge, Transpire has also engaged in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Transpire Inhaler Product. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, by engaging in the forgoing activities, Transpire specifically intends to infringe the '968 patent.

266. On information and belief, Transpire markets the Transpire Inhaler Product for co-development partnerships in which a pharmaceutical partner uses the Transpire Inhaler Product for an existing therapeutic. Ex. O. On information and belief, Transpire also markets the Transpire Inhaler Product for "strategic partnerships and licensing agreements to bring Transpire

Bio's early-stage and mid-stage therapeutic assets to market." *Id*. Finally, on information and belief, Transpire markets the Transpire Inhaler Product for commercialization partnerships for the commercialization of "Transpire Bio's early-entry, difficult-to-replicate asthma/COPD generic inhaled therapies." *Id*.

267. Accordingly, information and belief, Transpire's specific intent to actively induce and/or contribute to the infringement of at least claims 1 and 14 of the '968 patent includes the representations on Transpire's website offering to sell, market, and/or distribute the Transpire Inhaler Product to its customers and co-development and commercialization partners.

268. On information and belief, and with full knowledge of the '968 patent, Transpire intends to and has actively induced infringement of the '968 patent by offering the Transpire Inhaler Product to its customers and co-development and commercialization partners.

269. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, Transpire, with full knowledge of the '968 patent, knows that the Transpire Inhaler Product is especially adapted for use in a manner that infringes the '968 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1 and 14 of the '968 patent.

270. Any launch by Transpire of the Proposed ANDA Product before expiration of the '968 patent would cause GSK to suffer immediate and irreparable harm.

271. Unless Transpire is enjoined from infringing the '968 patent, actively inducing infringement of the '968 patent, and contributing to the infringement of others of the '968 patent, GSK will suffer irreparable injury. GSK has no adequate remedy at law.

272. Transpire's infringement of the '968 patent is willful.

COUNT VIII
DECLARATORY JUDGMENT OF
INFRINGEMENT OF THE '968 PATENT

273. GSK incorporates Paragraphs 1 through 47 and 57 through 69 as if fully set forth herein.

274. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

275. On information and belief, Transpire submitted the Transpire ANDA to obtain FDA approval to market its Proposed ANDA Product and is making preparations to launch, market, and sell the Proposed ANDA Product upon FDA approval. In addition, as evidenced on its website, Transpire is currently, or imminently will be, marketing and selling the Transpire Inhaler Product. These actions create an actual, immediate, and real controversy within the Declaratory Judgment Act that Transpire has directly or indirectly infringed or will directly or indirectly infringe at least one claim of each of the asserted patents by engaging in the commercial manufacture, use, offer to sell, sale or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product, or by actively inducing or contributing to that infringement of at least one claim of the '968 patent prior to its expiration.

276. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product and/or the Transpire Inhaler Product by Transpire before the expiration of the '968 patent would constitute infringement by Transpire of the '968 patent under 35 U.S.C. §§ 271(a)-(c).

277. On information and belief, and subject to GSK's ongoing investigation and discovery efforts, if Transpire's Proposed ANDA Product is approved, Transpire will make, use, offer for sale, sell, market, distribute, and/or import Transpire's Proposed ANDA Product,

comprising a medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions, and would infringe at least, by way of example, independent claims 1 and 14 of the ’968 patent.

278. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire’s preparations for making, offering for sale, selling, marketing, distributing, and/or importing the Transpire Inhaler Product, comprising a medicament dispenser for use with at least one medicament carrier carrying multiple distinct medicament portions, would infringe at least, by way of example, claims 1 and 14 of the ’968 patent.

279. Claims 1 and 14 of the ’968 patent recite as follows:

> 1. A medicament dispenser for containing plural elongate form medicament carriers, each medicament carrier having multiple distinct medicament dose portions carried thereby, said dispenser having a housing, and within said housing a dispensing mechanism for dispensing the distinct medicament dose portions carried by each of said plural medicament carriers, said mechanism comprising,
>
> a) at least one receiving station for receiving each of the plural medicament carriers;
>
> b) a release for releasing in combination a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said receiving station;
>
> c) an outlet, positioned to be in communication with the distinct medicament dose portions releasable by said release; and
>
> d) at least one indexer for individually indexing the distinct medicament dose portions of each of the plural medicament carriers, wherein said dispenser further comprises a movable cover for the outlet, wherein the cover:
>
> is movable from an at rest position, in which the cover covers the outlet, to a primed position and then an actuated position to uncover the outlet, and couples to the dispensing mechanism such that: movement of said cover from the primed position to the actuated position actuates one or more components of the dispensing mechanism, and movement of said cover from the at rest position to

the primed position does not actuate said one or more components of the dispensing mechanism.

14. A medicament dispenser for containing plural elongate blister strip form medicament carriers, each medicament carrier having multiple distinct medicament dose portions carried in multiple distinct pockets which are spaced along the length of and defined between peelable base and lid sheets secured to each other, said dispenser having a housing, and within said housing a dispensing mechanism for dispensing the distinct medicament dose portions carried by each of said plural medicament carriers, said mechanism comprising,

at least one receiving station for receiving each of the plural medicament carriers;

an opening station for receiving a pocket of each of said medicament carriers;

a release for releasing in combination a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said receiving station, comprising:

at least one peeler positioned to engage a base sheet and a lid sheet of a pocket which has been received in said opening station for peeling apart such a base sheet and lid sheet, to open such a pocket;

a lid take-up spindle for each medicament carrier for winding up the lid sheet thereon;

an outlet, positioned to be in communication with the distinct medicament dose portions releasable by said release and through which a user can access a medicament dose portion from an opened pocket; and

an index wheel for each medicament carrier for individually indexing the distinct pockets of each of the plural medicament carriers;

wherein said dispenser further comprises a movable cover that couples to the dispensing mechanism and that is movable from an at rest position, in which the cover covers the outlet, to a primed position and then an actuated position to uncover the outlet, and movement of the movable cover is coupled to the index wheels and lid take-up spindles by gearing that is arranged such that movement of the cover from the at rest position to the primed position does not result in any rotation of the index wheels and lid take-up spindles, but further movement of the cover to the actuated

position results in sufficient rotation of the index wheels and lid take-up spindles to advance each medicament carrier by one pocket distance.

280. On information and belief, Transpire's Proposed ANDA Product will have the same route of administration and dosage form as BREO ELLIPTA, which comprises an inhaler device. *See* 21 C.F.R. § 314.94(a)(6). Accordingly, on information and belief, Transpire's Proposed ANDA Product will comprise an inhaler device.

281. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser for containing plural elongate form medicament carriers, each medicament carrier having multiple distinct medicament dose portions carried thereby, said dispenser having a housing, and within said housing a dispensing mechanism for dispensing the distinct medicament dose portions carried by each of said plural medicament carriers. Exs. K, N (demonstrating use of Transpire's Rollingstar dry powder inhaler); Ex. K (showing Transpire's manufacture of medicament blister packs).

282. On information and belief, the Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising at least one receiving station for receiving each of the plural medicament carriers.

283. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a release for releasing in combination a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said receiving station.

284. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising an outlet, positioned to be in communication with the distinct medicament dose portions releasable by said release.

285. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising at least one indexer for individually indexing the distinct medicament dose portions of each of the plural medicament carriers, wherein said dispenser further comprises a movable cover for the outlet. Ex. K (showing cover that appears coupled to a dose indexer).

286. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a cover that is movable from an at rest position, in which the cover covers the outlet, to a primed position and then an actuated position to uncover the outlet, and couples to the dispensing mechanism such that: movement of said cover from the primed position to the actuated position actuates one or more components of the dispensing mechanism, and movement of said cover from the at rest position to the primed position does not actuate said one or more components of the dispensing mechanism. Ex. K (Rollingstar inhaler in closed position, with mouthpiece covered); *id.* (Rollingstar inhaler mouthpiece uncovered when in use).

287. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 1 of the '968 patent, and thus directly infringe claim 1 of the '968 patent, either literally or under the doctrine of equivalents.

288. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser for containing plural elongate blister strip

form medicament carriers, each medicament carrier having multiple distinct medicament dose portions carried in multiple distinct pockets which are spaced along the length of and defined between peelable base and lid sheets secured to each other, said dispenser having a housing, and within said housing a dispensing mechanism for dispensing the distinct medicament dose portions carried by each of said plural medicament carriers. Ex. K (showing Transpire's manufacture of medicament blister packs).

289. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a mechanism with at least one receiving station for receiving each of the plural medicament carriers.

290. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a mechanism with an opening station for receiving a pocket of each of said medicament carriers.

291. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a mechanism with a release for releasing in combination a distinct medicament dose portion from each of the plural medicament carriers on receipt thereof by said receiving station.

292. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a receiving station with at least one peeler positioned to engage a base sheet and a lid sheet of a pocket which has been received in said opening station for peeling apart such a base sheet and lid sheet, to open such a pocket.

293. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a receiving station with a lid take-up spindle for each medicament carrier for winding up the lid sheet thereon.

294. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a receiving station with an outlet, positioned to be in communication with the distinct medicament dose portions releasable by said release and through which a user can access a medicament dose portion from an opened pocket.

295. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a receiving station with an index wheel for each medicament carrier for individually indexing the distinct pockets of each of the plural medicament carriers. Ex. K (showing cover that appears coupled to a dose indexer).

296. On information and belief, Transpire's Proposed ANDA Product and the Transpire Inhaler Product comprise a medicament dispenser comprising a dispenser which further comprises a movable cover that couples to the dispensing mechanism and that is movable from an at rest position, in which the cover covers the outlet, to a primed position and then an actuated position to uncover the outlet, and movement of the movable cover is coupled to the index wheels and lid take-up spindles by gearing that is arranged such that movement of the cover from the at rest position to the primed position does not result in any rotation of the index wheels and lid take-up spindles, but further movement of the cover to the actuated position results in sufficient rotation of the index wheels and lid take-up spindles to advance each medicament carrier by one pocket distance. Ex. K (Rollingstar inhaler in closed position, with mouthpiece covered); *id.* (Rollingstar inhaler mouthpiece uncovered when in use).

297. Accordingly, on information and belief, and subject to GSK's ongoing investigation and discovery efforts, the manufacture, use (including as directed in Transpire's proposed labeling for Transpire's Proposed ANDA Product), offer for sale, sale, marketing, distribution, and/or importation of Transpire's Proposed ANDA Product and/or the Transpire

Inhaler Product will satisfy each of the recited elements of the medicament dispenser recited in at least claim 14 of the ’968 patent, and thus directly infringe claim 14 of the ’968 patent, either literally or under the doctrine of equivalents.

298. On information and belief, if the FDA were to approve the Transpire ANDA, Transpire’s commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product, including administration of Transpire’s Proposed ANDA Product according to the label instructions, would cause patients, physicians, prescribers, and/or other healthcare providers to directly infringe at least claims 1 and 14 of the ’968 patent. Transpire would actively induce and contribute to such direct infringement.

299. On information and belief, Transpire markets the Transpire Inhaler Product for co-development partnerships in which a pharmaceutical partner uses the Transpire Inhaler Product for an existing therapeutic. Ex. O. On information and belief, Transpire markets the Transpire Inhaler Product for “strategic partnerships and licensing agreements to bring Transpire Bio’s early-stage and mid-stage therapeutic assets to market.” *Id*. Finally, on information and belief, Transpire markets the Transpire Inhaler Product for commercialization partnerships for the commercialization of “Transpire Bio’s early-entry, difficult-to-replicate asthma/COPD generic inhaled therapies.” *Id*.

300. Accordingly, on information and belief, Transpire’s commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Transpire Inhaler Product would cause its customers and co-development and commercialization partners to directly infringe at least claims 1 and 14 of the ’968 patent. Transpire would actively induce and contribute to such direct infringement.

301. On information and belief, Transpire has knowledge of the claims of the ’968 patent at least by virtue of the ’968 patent’s prior listing in the Orange Book for BREO ELLIPTA. Despite this knowledge, Transpire has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing (including marketing Transpire’s Proposed ANDA Product as a generic substitute for BREO ELLIPTA to be used and administered in the same manner as BREO ELLIPTA), distribution, and/or importation of Transpire’s Proposed ANDA Product with the proposed labeling to be included for the Proposed ANDA Product, immediately and imminently upon approval of ANDA No. 218914. Moreover, despite knowledge of the ’968 patent, Transpire has made preparations to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Transpire Inhaler Product. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, by engaging in the forgoing activities, Transpire specifically intends to infringe the ’968 patent.

302. On information and belief, Transpire’s specific intent to actively induce and/or contribute to infringement of at least claims 1 and 14 of the ’968 patent includes Transpire’s decision to proceed with its plan to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Transpire’s Proposed ANDA Product, despite being aware that the proposed labeling to be included for the Proposed ANDA Product instructs, directs, recommends, encourages, and/or promotes direct infringement of the ’968 patent.

303. Further, on information and belief, Transpire’s specific intent to actively induce and/or contribute to the infringement of at least claims 1 and 14 of the ’968 patent includes the representations on Transpire’s website offering to sell, market, and/or distribute the Transpire Inhaler Product to its customers and co-development and commercialization partners.

304. On information and belief, and with full knowledge of the ’968 patent, Transpire intends to and will actively induce infringement of the ’968 patent when Transpire’s Proposed ANDA is approved and will do so immediately and imminently upon approval.

305. On information and belief, and with full knowledge of the ’968 patent, Transpire intends to and has actively induced infringement of the ’968 patent by offering the Transpire Inhaler Product to its customers and co-development and commercialization partners.

306. BREO ELLIPTA and any corresponding generic fluticasone furoate and vilanterol trifenatate inhalation powder product is not a staple article of commerce and has no substantial approved uses that do not infringe at least claims 1 and 14 of the ’968 patent. On information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire, with full knowledge of the ’968 patent, knows that its Proposed ANDA Product is especially adapted for use in a manner that infringes the ’968 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1 and 14 of the ’968 patent. Further, on information and belief, and subject to GSK’s ongoing investigation and discovery efforts, Transpire, with full knowledge of the ’968 patent, knows that the Transpire Inhaler Product is especially adapted for use in a manner that infringes the ’968 patent, is not a staple article of commerce, and has no substantial uses that do not infringe at least claims 1 and 14 of the ’968 patent.

307. Any launch by Transpire of the Proposed ANDA Product before expiration of the ’968 patent would cause GSK to suffer immediate and irreparable harm.

308. Unless Transpire is enjoined from infringing the ’968 patent, actively inducing infringement of the ’968 patent, and contributing to the infringement of others of the ’968 patent, GSK will suffer irreparable injury. GSK has no adequate remedy at law.

309. Transpire's infringement of the '968 patent is willful.

310. For at least the above reasons, a definite and concrete controversy exists between GSK and Transpire as to whether Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product prior to the expiration of the '968 patent would infringe the '968 patent. Accordingly, GSK is entitled to a declaratory judgment that it would.

COUNT IX
INFRINGEMENT OF REGISTERED TRADEMARK
(15 U.S.C. § 1114(1))

311. GSK incorporates Paragraphs 1 through 15, 48 through 56, and 70 through 85 as if fully set forth herein.

312. The Ellipta Trade Dress is distinctive and of incalculable value, and is exclusively associated in the public mind with GSK's ELLIPTA goods and services.

313. GSK is the owner of the Ellipta Trade Dress and of U.S. Trademark Registration Nos. 6,150,524; 6,150,525; 4,549,525; 4,549,536; 4,549,527 covering the Ellipta Trade Dress.

314. Without GSK's authorization or license, and on information and belief, with knowledge of GSK's prior rights in the Ellipta Trade Dress, Transpire has manufactured, advertised, offered for sale, sold, distributed, imported, and/or exported Infringing Products bearing the Ellipta Trade Dress or an Infringing Inhaler Design highly similar thereto.

315. On information and belief, Transpire was on actual notice of GSK's prior exclusive rights in the Ellipta Trade Dress. In addition, GSK's federal registrations covering the Ellipta Trade Dress put Transpire on constructive notice of GSK's prior exclusive rights in the Ellipta Trade Dress.

316. Transpire's manufacturing, advertisement, offering for sale, sale, distribution, import, and/or export of Infringing Products identical or highly similar to GSK's authorized products bearing the Ellipta Trade Dress is likely to cause confusion, mistake, or deception as to the source or sponsorship of Transpire's goods. As a result of Transpire's use of an Infringing Inhaler Design identical or highly similar to GSK's protected Ellipta Trade Dress, the public is likely to believe that Transpire's goods have been manufactured or approved by GSK.

317. Transpire's infringement of the Ellipta Trade Dress is willful, intended to reap the benefit of the goodwill of GSK, and violates Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1).

318. Transpire's aforesaid conduct has caused, and unless enjoined by this Court, will continue to cause, GSK to sustain irreparable damage, loss, and injury, for which GSK has no adequate remedy at law.

COUNT X
UNFAIR COMPETITION IN VIOLATION OF 15 U.S.C. § 1125(a)

319. GSK incorporates Paragraphs 1 through 15, 48 through 56, and 70 through 85 as if fully set forth herein.

320. The Ellipta Trade Dress is distinctive and of incalculable value, and is associated in the public mind with GSK's goods and services.

321. Without GSK's authorization or license, and on information and belief, with knowledge of GSK's prior exclusive rights in the Ellipta Trade Dress, Transpire has manufactured, advertised, offered for sale, sold, distributed, imported, and/or exported Infringing Products bearing the Ellipta Trade Dress or an Infringing Inhaler Design highly similar thereto.

322. Transpire's conduct as outlined herein is likely to cause confusion, cause mistake, and/or deceive as to the affiliation, connection, or association between GSK and Transpire,

and/or as to GSK's sponsorship or approval of Transpire's goods, services, and/or commercial activities.

323. As a result of the foregoing, Transpire has falsely designated the origin of its products in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

324. On information and belief, Transpire's conduct has been undertaken knowingly, willfully, and in bad faith.

325. Transpire's aforesaid conduct has caused, and unless enjoined by this Court, will continue to cause, GSK to sustain irreparable damage, loss, and injury, for which GSK has no adequate remedy at law.

COUNT XI
FLORIDA COMMON LAW
TRADEMARK INFRINGEMENT AND UNFAIR COMPETITION

326. GSK incorporates Paragraphs 1 through 15, 48 through 56, and 70 through 85 as if fully set forth herein.

327. The Ellipta Trade Dress is distinctive and of incalculable value, and is associated by consumers in the State of Florida with GSK's goods and services.

328. Transpire's manufacturing, advertisement, offering for sale, sale, distribution, import, and/or export of Infringing Products bearing an Infringing Inhaler Design that is identical or highly similar to the Ellipta Trade Dress is likely to cause confusion, mistake, or deception as to the source or sponsorship of Transpire's goods in violation of GSK's rights in the Ellipta Trade Dress in the State of Florida.

329. As a result of Transpire's unauthorized use of an Infringing Inhaler Design that is identical or highly similar to GSK's protected Ellipta Trade Dress, the Florida public is likely to believe that Transpire's goods have been manufactured or approved by GSK.

330. Transpire has engaged in this conduct knowingly, willfully, and in bad faith, justifying an assessment of increased, exemplary, and punitive damages against Transpire in an amount to be determined at trial.

331. Transpire's aforesaid conduct has caused, and unless enjoined by this Court, will continue to cause, GSK to sustain irreparable damage, loss, and injury, for which GSK has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, GSK respectfully requests the following relief:

A. A judgment that Transpire has infringed the Patents-in-Suit, and a declaration that Transpire's commercial manufacture, distribution, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Proposed ANDA Product and/or the Transpire Inhaler Product would infringe the Patents-in-Suit;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the Transpire ANDA No. 218914 under § 505(j) of the Federal Food Drug, and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration of the Patents-in-Suit;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining Transpire, their respective officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the Patents-in-Suit for the full term thereof;

D. An order that damages or other monetary relief be awarded to GSK if Transpire engages in the commercial manufacture, use, marketing, offer to sale, sale, and/or importation of the Proposed ANDA Product and/or the Transpire Inhaler Product prior to the expiration of the

Patents-in-Suit for the full term thereof, and that such damages or monetary relief be trebled and awarded to GSK with prejudgment and post-judgment interest;

E. A judgment that Transpire has violated 15 U.S.C. § 1114 by infringing GSK's registered trademarks and trade dress;

F. A judgment that Transpire has violated 15 U.S.C. § 1125(a) by unfairly competing against GSK by using the Ellipta Trade Dress or an infringing design confusingly similar thereto;

G. A permanent injunction restraining and enjoining Transpire, their respective officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the Ellipta Trade Dress;

H. An order requiring Transpire to abandon the Transpire Applications with prejudice;

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

J. Costs and expenses incurred by GSK in this action; and

K. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

GSK requests a trial by jury of all claims that can be so tried.

Dated: September 25, 2025

Respectfully submitted,

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