IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

GLAXO GROUP LIMITED and GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LIMITED, *Plaintiffs*, v. TRANSPIRE BIO INC. *Defendant*.	Civil Action No. _____

COMPLAINT

Plaintiffs Glaxo Group Limited ("Glaxo Group") and GlaxoSmithKline Intellectual Property Development Limited ("GSK IP") (collectively, "GSK"), for its complaint against Defendant Transpire Bio Inc. ("Transpire"), hereby allege as follows:

NATURE OF ACTION

1. This action arises from Transpire's willful infringement of GSK's valuable patent and trademark rights.

2. GSK is the maker of BREO, a prescription pharmaceutical that combines two different active ingredients—fluticasone furoate and vilanterol trifenatate—for simultaneous administration from a patient's single inhalation to treat asthma and chronic obstructive pulmonary disease ("COPD"). Along with several other pharmaceutical products offered by GSK, BREO is administered through the ELLIPTA inhaler, a revolutionary dry powder inhaler that provides for increased versatility in treatment options including monotherapies and combination therapies and allows medications to be held separately until the point of inhalation.

The ELLIPTA products, including BREO ELLIPTA, allow for once-daily treatment in three simple principal operating steps that increase ease of use for the patient: (1) open, (2) inhale, and (3) close. The BREO ELLIPTA product is protected by multiple patents in the United States including GSK's United States Patent Nos. 11,116,721 ("'721 patent"), 8,534,281 ("'281 patent"), 8,746,242 ("'242 patent"), and 8,161,968 ("'968 patent") (collectively, the "Patents-in-Suit").

3. In part due to the enormous success of GSK's BREO ELLIPTA product, the unique shape and overall design of the ELLIPTA inhaler (the "Ellipta Trade Dress") have become instantly recognizable to the public as exclusively denoting GSK and the high quality of GSK's goods offered under that mark, and GSK has developed protectable secondary meaning in the Ellipta Trade Dress. The Ellipta Trade Dress is a registered trademark in the United States.

4. Transpire now seeks to break into this market. But rather than compete fairly, Transpire has decided to copy GSK's valuable intellectual property. Transpire submitted Abbreviated New Drug Application ("ANDA") No. 218914 (the "Transpire ANDA") seeking approval from the U.S. Food & Drug Administration ("FDA") to make a generic version of GSK's BREO ELLIPTA (fluticasone furoate, vilanterol trifenatate) product. The product that is the subject of ANDA No. 218914 (the "Proposed ANDA Product") infringes the Patents-in-Suit. In addition, Transpire's website advertises an infringing knock-off dry powder inhaler (the "Transpire Inhaler Product," and together with the Proposed ANDA Product, the "Infringing Products") for co-development and commercialization partnerships.

5. Not content to merely copy the *function* of GSK's BREO ELLIPTA product, Transpire has opted to misappropriate its distinctive trade dress as well. The Infringing Products

copy nearly every aspect of the protected Ellipta Trade Dress and are almost identical to the BREO ELLIPTA inhaler marketed under the Ellipta Trade Dress:

BREO ELLIPTA Inhaler

Infringing Product

6. GSK therefore seeks a judgment under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and declaratory judgment under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that Transpire's commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation into the United States of the Infringing Products would directly and indirectly infringe the Patents-in-Suit. GSK also brings claims for trademark and trade dress infringement under Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1); unfair competition under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); and related claims under Florida common law.

PARTIES

7. Plaintiff Glaxo Group is a corporation organized and existing under the laws of England and Wales, having a principal place of business at GSK Medicines Research Centre, Gunnels Wood Road, Stevenage SG1 2NY, United Kingdom. Glaxo Group develops, manufactures, and markets pharmaceutical products in the United States. Glaxo Group is the owner of the '721 patent, '242 patent, '281 patent, and '968 patent. Glaxo Group is also the

owner of U.S. Trademark Registration Nos. 4,549,525; 4,549,526; 4,549,527; 6,150,524; and 6,150,525 covering the Ellipta Trade Dress.

8. Plaintiff GSK IP is a corporation organized and existing under the laws of England and Wales, having a principal place of business at GSK Medicines Research Centre, Gunnels Wood Road, Stevenage SG1 2NY, United Kingdom. GSK IP develops, manufactures, and markets pharmaceutical products in the United States. GSK IP is the holder of New Drug Application No. 204275.

9. On information and belief, Defendant Transpire is a corporation organized under the laws of the State of Florida, having a principal place of business at 1300 Concord Terrace, Suite 310, Sunrise, Florida 33323. On information and belief, Transpire has a registered agent for service of process, Xianming Zeng, located at Suite A, 2945 West Corporate Lakes Blvd., Weston, Florida 33331. On information and belief, Transpire is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the United States market, including in this judicial district.

10. On information and belief, Transpire prepared and submitted ANDA No. 218914 to the FDA.

11. On information and belief, upon FDA approval, Transpire will make, use, offer to sell, and/or sell the inhaler product and the drug products that are the subject of ANDA No. 218914 throughout the United States, and/or import such products into the United States, including in this judicial district.

12. On information and belief, Transpire will derive significant financial benefit resulting from the FDA's approval of ANDA No. 218914 and subsequent marketing and use of

Transpire's Proposed ANDA Product and/or the Transpire Inhaler Product throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a)-(b), 2201, and 2202, and 15 U.S.C. § 1121. Supplemental jurisdiction exists over GSK's state law claims under 28 U.S.C. § 1367(a).

14. This Court has personal jurisdiction over Transpire because, on information and belief, Transpire is a Florida corporation headquartered in Florida. On information and belief, Transpire maintains pervasive, continuous, and systematic contacts with the State of Florida through the making, marketing, distribution, and/or sale of generic versions of branded pharmaceutical products and inhaler products in the State of Florida and by deriving substantial revenue from the importation and sale of its products in the State of Florida.

15. Venue is proper in this district as to Transpire, pursuant to 28 U.S.C. §§ 1391 and 1400(b), because Transpire is incorporated in the State of Florida, because Transpire resides in this judicial district, and because a substantial portion of the events giving rise to the claims occurred in this district.

THE DRUG APPROVAL PROCESS

16. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (commonly called the "Hatch-Waxman Act") to strike a balance between providing incentives for innovative new drugs while also providing a mechanism and incentive for drug manufacturers to make generic versions of drugs. Pub. L. No. 98-417, 98 Stat. 1585 (1984). Under the Hatch-Waxman framework, described further below, Congress created a requirement for innovating drug manufactures to provide notice of certain types of patents that

cover its drug and a mechanism for early resolution of patent disputes before a generic drug maker has begun marketing. *See generally Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *Caraco Pharm. Labs. Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008); H.R. Rep. No. 98-857, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2679.

17. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). Under the Hatch-Waxman framework, the sponsor of the NDA is required to submit to the FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and the FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1), (c)(2).

18. Alternatively, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and the FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "reference listed drug" or "branded drug").

19. In conjunction with this "abbreviated" application process, Congress has put in place a process for early resolution of patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify, for instance, that it believes a patent is invalid or will not be infringed

by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a "Paragraph IV Certification."

20. The filer of an ANDA with a Paragraph IV Certification must also provide notice to both the owner of the listed patents and the holder of the NDA for the referenced listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. *See* 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

21. Congress also created a so-called "artificial" act of infringement under 35 U.S.C. § 271(e)(2) "that consists of submitting an ANDA . . . containing a [Paragraph IV Certification]." *Eli Lilly*, 496 U.S. at 678. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is subject to a thirty-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The stay provides an opportunity for the parties to resolve any patent disputes before the generic product enters the market. *See* 21 U.S.C. 355(j)(5)(B)(iii).

FACTUAL BACKGROUND

The Patents-in-Suit

22. On September 14, 2021, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '721 patent, entitled "Pharmaceutical formulations comprising 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl) phenol," to Glaxo Group as the assignee. A true and correct copy of the '721 patent is attached as Exhibit A.

23. Glaxo Group owns the ’721 patent and has all substantial rights in and to the ’721 patent, including the right to assert any claims for past, present, and future infringement of the ’721 patent.

24. The claims of the ’721 patent are generally directed to novel dry powder pharmaceutical formulations comprising fluticasone furoate and vilanterol, and methods of using them.

25. On June 10, 2014, the USPTO duly and legally issued the ’242 patent, entitled “Medicament Dispenser,” to Glaxo Group as the assignee. A true and correct copy of the ’242 patent is attached as Exhibit B.

26. Glaxo Group owns the ’242 patent and has all substantial rights in and to the ’242 patent, including the right to assert any claims for past, present, and future infringement of the ’242 patent.

27. On September 17, 2013, the USPTO duly and legally issued the ’281 patent, entitled “Manifold for Use in Medicament Dispenser,” to Glaxo Group as the assignee. A true and correct copy of the ’281 patent is attached as Exhibit C.

28. Glaxo Group owns the ’281 patent and has all substantial rights in and to the ’281 patent, including the right to assert any claims for past, present, and future infringement of the ’281 patent.

29. On April 24, 2012, the USPTO duly and legally issued the ’968 patent, entitled “Medicament Dispenser,” to Glaxo Group as the assignee. A true and correct copy of the ’968 patent is attached as Exhibit D.

30. Glaxo Group owns the ’968 patent and has all substantial rights in and to the ’968 patent, including the right to assert any claims for past, present, and future infringement of the ’968 patent.

31. The claims of the ’242 patent, ’281 patent, and ’968 patent are generally directed to GSK’s innovations to develop a next generation, convenient, and easy to use dry powder inhaler that allows greater versatility in treatment options with single or multiple strip configurations that can hold distinct medicine formulations including combination therapies of beta-agonist bronchodilators, corticosteroid anti-inflammatories, and other active ingredients.

BREO ELLIPTA

32. GSK IP is the holder of NDA No. 204275, including all supplements thereto, for BREO ELLIPTA.

33. On July 11, 2012, GSK submitted NDA No. 204275, under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), seeking FDA approval for inhalation powders for oral inhalation comprising fluticasone furoate and vilanterol trifenatate. On May 10, 2013, the FDA approved NDA No. 204275.

34. GSK timely submitted information regarding ’721 patent for listing in the FDA’s Orange Book with respect to BREO ELLIPTA, for strengths 0.1MG/INH (100 mcg) fluticasone furoate, EQ 0.025MG BASE/INH (25 mcg) vilanterol trifenatate (Product 001) (“100/25 dosage strength”); 0.2MG/INH (200 mcg) fluticasone furoate, EQ 0.025MG BASE/INH (25 mcg) vilanterol trifenatate (Product 002) (“200/25 dosage strength”); and 0.05MG/INH (500 mcg) fluticasone furoate, EQ 0.025MG BASE/INH (25 mcg) vilanterol trifenatate (Product 003) (“500/25 dosage strength”), pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2). The FDA thereafter

listed the ’721 Patent in the Orange Book with respect to those products, pursuant to 21 C.F.R. § 314.53(e).

35. GSK timely submitted information regarding the ’242 patent for listing in the FDA’s Orange Book with respect to BREO ELLIPTA, for strengths 0.1MG/INH fluticasone furoate, EQ 0.025MG BASE/INH vilanterol trifenatate (Product 001); 0.2MG/INH fluticasone furoate, EQ 0.025MG BASE/INH vilanterol trifenatate (Product 002); and 0.05MG/INH fluticasone furoate, EQ 0.025MG BASE/INH vilanterol trifenatate (Product 003), pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2). The FDA thereafter listed the ’242 patent in the Orange Book with respect to those products, pursuant to 21 C.F.R. § 314.53(e).

36. GSK timely submitted information regarding the ’281 patent for listing in the FDA’s Orange Book with respect to BREO ELLIPTA, for strengths 0.1MG/INH fluticasone furoate, EQ 0.025MG BASE/INH vilanterol trifenatate (Product 001); 0.2MG/INH fluticasone furoate, EQ 0.025MG BASE/INH vilanterol trifenatate (Product 002); and 0.05MG/INH fluticasone furoate, EQ 0.025MG BASE/INH vilanterol trifenatate (Product 003), pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2). The FDA thereafter listed the ’281 patent in the Orange Book with respect to those products, pursuant to 21 C.F.R. § 314.53(e).

37. GSK timely submitted information regarding the ’968 patent for listing in the FDA’s Orange Book with respect to BREO ELLIPTA, for strengths 0.1MG/INH fluticasone furoate, EQ 0.025MG BASE/INH vilanterol trifenatate (Product 001); 0.2MG/INH fluticasone furoate, EQ 0.025MG BASE/INH vilanterol trifenatate (Product 002); and 0.05MG/INH fluticasone furoate, EQ 0.025MG BASE/INH vilanterol trifenatate (Product 003), pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2). The FDA thereafter listed the ’968 patent in the Orange Book with respect to those products, pursuant to 21 C.F.R. § 314.53(e). On May 7, 2025, GSK

submitted a request to the FDA to withdraw the '968 patent from the Orange Book with respect to BREO ELLIPTA pursuant to 21 C.F.R. § 314.53(f)(2)(iv).

38. The FDA-approved label for BREO ELLIPTA ("BREO ELLIPTA Label" or "Label") provides information and instructions for the safe and effective use of BREO ELLIPTA by healthcare providers and patients, among other things. A true and correct copy of the BREO ELLIPTA Label is attached as Exhibit E.

39. BREO ELLIPTA is indicated for the "maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)." Ex. E § 1.1, Maintenance Treatment of Chronic Obstructive Pulmonary Disorder. According to the BREO ELLIPTA Label, "COPD is a chronic lung disease that includes chronic bronchitis, emphysema, or both." *Id.*, Patient Information. Additionally, BREO ELLIPTA is indicated for the "maintenance treatment of asthma in patients aged 5 years and older." Ex. E § 1.2, Treatment of Asthma.

40. As stated in the BREO ELLIPTA Label, "BREO ELLIPTA is an inhalation powder drug product for delivery of a combination of fluticasone furoate (an ICS) and vilanterol (a LABA) to patients by oral inhalation." Ex. E, § 11. "Fluticasone furoate, a synthetic trifluorinated corticosteroid has the chemical name (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," which is 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." *Id.* § 11, Description. Additionally, "[v]ilanterol trifenatate has the chemical name triphenylacetic acid-4-{(1R)-2-[(6-{2-[2,6-dicholorobenzyl)oxy]ethoxy}hexyl) amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol (1:1)," a pharmaceutically acceptable salt of 4-{(1R)-2-

[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxyl}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol. *See id.*

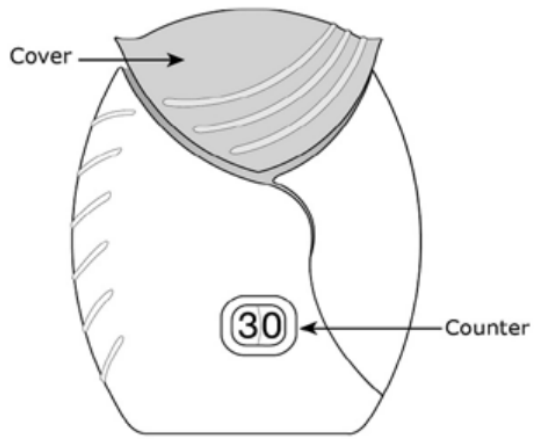
41. Fluticasone furoate is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. Ex. E § 12.1, Mechanism of Action. Inflammation is a key driver of COPD and asthma pathogenesis. *Id.* Corticosteroids have been shown to exert broad anti-inflammatory effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) involved in inflammation. *Id.* Fluticasone furoate has also been shown to activate glucocorticoid response elements, inhibit pro-inflammatory transcription factors, and inhibit antigen-induced lung eosinophilia in sensitized rats. *Id.* These mechanisms likely underlie the clinical efficacy of fluticasone furoate. *Id.*

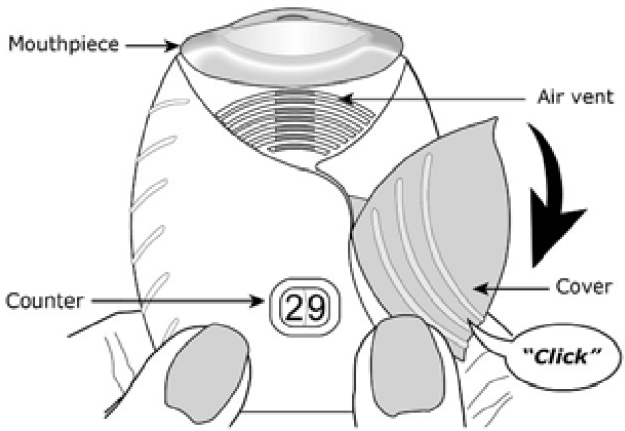
42. Vilanterol is a class of drug known as long-acting beta$_2$-adrenergic agonist ("LABA"). Ex. E § 12.1, Mechanism of Action. Beta$_2$-receptors are the predominant adrenergic receptors in bronchial smooth muscle but are also found in the heart. *Id.* The pharmacologic effects of beta$_2$-adrenoceptor agonist drugs, including vilanterol, are at least in part attributable to stimulation of intracellular adenyl cyclase, the enzyme that catalyzes the conversion of adenosine triphosphate (ATP) to cyclic-3',5'-adenosine monophosphate (cyclic AMP). *Id.* Increased cyclic AMP levels cause relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells. *Id.*

43. As further stated in the BREO ELLIPTA Label, "the recommended dosage of BREO ELLIPTA 100/25 mcg (containing fluticasone furoate 100 mcg and vilanterol 25 mcg) is 1 actuation once daily by oral inhalation," for the maintenance treatment of COPD in adults and the maintenance treatment of asthma in adults and pediatric patients aged 12 to 17 years. Ex. E §

2, Dosage and Administration. Further, the BREO ELLIPTA dosage form is "supplied as a disposable light gray and pale blue plastic inhaler containing 2 foil strips, each with 30 blisters (or 14 blistered for the institutional pack)." *Id.*, § 16, How Supplied/Storage & Handling. "Each blister on one strip contains a white powder blend of micronized fluticasone furoate (50, 100, or 200 mcg) and lactose monohydrate (12.5, 12.4 or 12.3 mg, respectively), and each blister on the other strip contains a white powder mix of micronized vilanterol trifenatate (40 mcg equivalent to 25 mcg of vilanterol), magnesium stearate (125 mcg), and lactose monohydrate (12.34 mg)." *Id.*, § 11, Description.

44. The BREO ELLIPTA Label includes diagrams identifying features of the inhaler device. Ex. E, Instructions for Use. For example, the Label identifies the "cover," which can slide open to expose the "mouthpiece." *Id.* It also identifies an "air vent" comprising multiple openings, situated directly below the mouthpiece. *Id.*





Id., Figs. C-D.

45. The BREO ELLIPTA Label instructs that "[b]efore the inhaler is used for the first time, the counter should show the number 30 (14 if you have a sample or institutional pack). This is the number of doses in the inhaler." Ex. E, Instructions for Use. Further, "[e]ach time

you open the cover, you prepare 1 dose of medicine." *Id.* The Label further instructs the reader to "[s]lide the cover down to expose the mouthpiece. You should hear a 'click.' The counter will count down by 1 number." *Id.*

46. The BREO ELLIPTA Label provides that "[a]fter the inhaler is activated, the powder within both blisters is exposed and ready for dispersion into the airstream created by the patient inhaling through the mouthpiece." Ex. E, § 11, Description.

Id., Fig. F.

47. When using the inhaler to obtain a dose of medicament, the BREO ELLIPTA Label specifically instructs the user "not [to] block the air vent with your fingers," (Ex. E, Instruction for Use), as shown below:

Id., Fig. G.

The Ellipta Trade Dress

48. GSK offers five prescription pharmaceutical products in the ELLIPTA inhaler: namely, BREO ELLIPTA (consisting of fluticasone furoate and vilanterol) ANORO ELLIPTA (umeclidinium and vilanterol), INCRUSE ELLIPTA (umeclidinium), ARNUITY ELLIPTA (fluticasone furoate), and TRELEGY ELLIPTA (fluticasone furoate, umeclidinium, and vilanterol) (collectively, the "Ellipta Portfolio Products"). All of the Ellipta Portfolio Products are provided in GSK's distinctive ELLIPTA inhaler bearing the Ellipta Trade Dress, which consists of an overall rounded shape, a moveable closure with an overall triangular shape and three curved lines on the top of the device and six curved lines on the side of the device, as shown below:

49. GSK has extensively advertised and promoted the products manufactured, sold, and offered for sale under the Ellipta Trade Dress. Since the launch of the first Ellipta Portfolio Product in 2013, GSK has devoted significant resources to marketing Ellipta Portfolio Products (including in television, print, Internet, radio, and outdoor media) to prescribing physicians, pharmacists, and consumers in the United States. GSK's advertising and promotion of Ellipta Portfolio Products has consistently and prominently featured the unique Ellipta Trade Dress.

50. GSK's Ellipta Portfolio Products sold under the ELLIPTA Trade Dress are available throughout the United States and have enjoyed considerable commercial success.

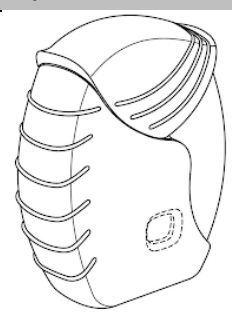
51. Due to GSK's extensive use and promotion of the Ellipta Trade Dress, the Ellipta Trade Dress immediately indicates that GSK is the exclusive source of the pharmaceutical products contained within ELLIPTA inhalers.

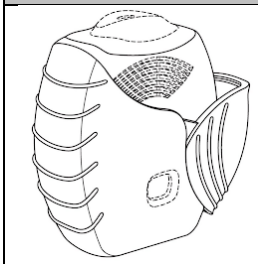
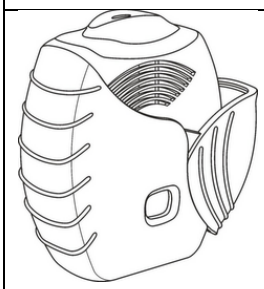
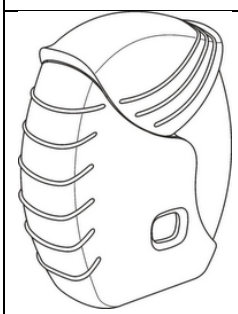
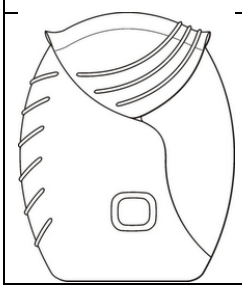
52. Patients who use medications provided under the Ellipta Trade Dress have come to identify the Ellipta Trade Dress as source identifying of GSK and as an indication of quality. In order to ensure that these patients receive the consistency, reliability, and above all safety that they have come to expect, the Ellipta Portfolio Products provided by GSK under the Ellipta Trade Dress are subject to exacting quality control standards.

53. As a result of GSK's significant investment of time, money, and effort promoting the Ellipta Trade Dress, as well as the widespread sales of products bearing the Ellipta Trade Dress, the Ellipta Trade Dress has acquired enormous value and has become extremely well-known to the consuming public and trade as identifying and distinguishing the source of GSK's products exclusively and uniquely.

54. As a result, the Ellipta Trade Dress has come to represent enormous goodwill of GSK and is a valuable asset of GSK, and GSK owns protectable common law rights in the Ellipta Trade Dress.

55. The Ellipta Trade Dress is also protected by a number of federal trademark registrations owned by GSK, as follows (collectively, the "Ellipta Trademark Registrations"):

Mark	***Reg. No.***	***Reg. Date***	***Registered Goods***
	6,150,524	September 15, 2020	Class 5: Inhalers filled with pharmaceutical preparations for the treatment and alleviation of respiratory disorders

Mark	***Reg. No.***	***Reg. Date***	***Registered Goods***
	6,150,525	September 15, 2020	Class 5: Inhalers filled with pharmaceutical preparations for the treatment and alleviation of respiratory disorders
	4,549,525 (Supplemental Register)	June 10, 2014	Class 5: Inhalers filled with pharmaceutical preparations for the treatment and alleviation of respiratory disorders
	4,549,526 (Supplemental Register)	June 10, 2014	Class 5: Inhalers filled with pharmaceutical preparations for the treatment and alleviation of respiratory disorders
	4,549,527 (Supplemental Register)	June 10, 2014	Class 5: Inhalers filled with pharmaceutical preparations for the treatment and alleviation of respiratory disorders

56. These registrations are all valid, subsisting, and in full force and effect. Moreover, the two registrations on the Principal Register, Reg. Nos. 6,150,524 and 6,150,525, have become incontestable under Section 15 of the Lanham Act, 15 U.S.C. § 1065, and therefore serve as conclusive evidence of the validity of the registered marks, of the registration of those marks, and of GSK's exclusive right to use those marks in commerce on or in connection with the products for which the marks are registered, as provided by Section 33(b) of the Lanham Act,

15 U.S.C. § 1115(b). Printouts detailing the registration information for the above marks are attached hereto as Exhibits F through J.

Transpire's Proposed ANDA Product and the Transpire Inhaler Product Infringe GSK's Patents

57. On information and belief, on or before August 12, 2025, Transpire submitted ANDA No. 218914 pursuant to 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, importation, use, marketing, and sale of proposed generic fluticasone furoate 100 mcg/inhalation equivalent and vilanterol trifenatate 25 mcg/inhalation equivalent inhalation powder and referencing GSK's BREO ELLIPTA product as the reference listed drug.

58. On information and belief, Transpire manufactures, uses, offers for sale, sells, markets, distributes, and/or imports a dry powder inhaler, namely its Transpire Inhaler Product, for various clinical applications, including the treatment of asthma and COPD. For example, Transpire's website states:

- "We have developed commercial scale, clinical-stage inhalation formulation technologies and delivery platforms that are fully customizable to different clinical applications." Ex. K.
- "Transpire Bio is developing multiple proprietary inhalation technology platforms, including dry powder inhalers, metered-dose inhalers, and soft-mist inhalers." Ex. L.
- "Our inhalation technology platforms have wide applicability and can support small molecules, polypeptides, protein, oligonucleotides, biologics, and vaccines." Ex. K.
- "We are developing early-to-market, difficult-to-replicate asthma/COPD generic inhaled therapies, and partnering for their commercialization." Ex. M.

59. On information and belief, Transpire's Proposed ANDA Product incorporates the Transpire Inhaler Product to administer its generic version of BREO.

60. On information and belief, Transpire sells, offers for sale, markets, distributes, and/or imports its Transpire Inhaler Product under the name "Rollingstar," shown below on the left:

Ex. K. According to Transpire's trademark submissions to the USPTO, Transpire has been offering the Transpire Inhaler Product for sale since at least as early as September 3, 2024.

61. Transpire's website also depicts the Transpire Inhaler Product with its cover in the open position when in use. Ex. N. When the cover is open, the Transpire Inhaler Product reveals a mouthpiece with air vents situated directly beneath it, as pictured below: