IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VECTURA LIMITED,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
GLAXOSMITHKLINE LLC and GLAXO GROUP LIMITED	)	
	)	
	)	**JURY TRIAL DEMANDED**
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Vectura Limited ("Vectura"), for its Complaint against Defendants GlaxoSmithKline LLC ("GSK") and Glaxo Group Limited ("GGL") (collectively, "Glaxo"), hereby alleges as follows:

THE PARTIES

1. Vectura is a corporation organized and existing under the laws of the United Kingdom, having its principal place of business at One Prospect West, Chippenham, Wiltshire SN14 6FH, United Kingdom.

2. On information and belief, GlaxoSmithKline LLC is a Delaware limited liability company and has headquarters in Philadelphia, Pennsylvania and Research Triangle Park, North Carolina.

3. On information and belief, Defendant Glaxo Group Limited is a corporation organized under the laws of Great Britain, having a principal place of business at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB06 0NN, United Kingdom.

4. On information and belief, Glaxo is in the business of, among other things, manufacturing, marketing, importing, preparing, and selling pharmaceutical products that it distributes in the State of Delaware and throughout the United States.

NATURE OF ACTION

5. This is an action for infringement of United States Patent No. 8,303,991 ("the '991 patent") under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, including 35 U.S.C. §§271(a) and 271(b). A true and correct copy of the '991 patent is attached as Exhibit A.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over GSK because it is a corporation organized and existing under the laws of the State of Delaware, has systematic and continuous contacts with this judicial district, and has committed acts of patent infringement giving rise to this action within this judicial district, including by placing and/or by inducing GGL to place BREO® ELLIPTA® 100/25 (fluticasone furoate 100 mcg and vilanterol 25 mcg inhalation powder), BREO® ELLIPTA® 200/25 (fluticasone furoate 200 mcg and vilanterol 25 mcg inhalation powder) (collectively, **"Breo®"**), ANORO® ELLIPTA® (umeclidinium and vilanterol inhalation powder) **("Anoro®"**), and INCRUSE® ELLIPTA® (umeclidinium inhalation powder) **("Incruse®"**) products into the stream of commerce in this district, such that GSK reasonably should have anticipated being subject to suit in this judicial district.

8. This Court has personal jurisdiction over GGL because it has committed acts of patent infringement giving rise to this action within this judicial district, including by placing and/or by inducing GSK to place Breo®, Anoro®, and Incruse® products into the stream of

commerce in this district, such that GGL reasonably should have anticipated being subject to suit in this judicial district.

9. In the alternative, to the extent that GGL is otherwise not subject to the jurisdiction of this Court or of any other United States District Court, this Court has personal jurisdiction over GGL pursuant to Federal Rule of Civil Procedure 4(k)(2). This complaint arises under federal law and GGL has sufficient contacts with the U.S. as a whole to satisfy due process standards and justify application of federal law because, *inter alia*, GGL (a) directly, or through its subsidiaries, including GSK, manufactures, offers for sale, sells, and/or imports pharmaceutical drug products, including Breo®, Anoro®, and Incruse®, throughout the U.S.; (b) prioritizes investment in the growth of core therapeutic areas in the U.S. as part of its global business plan; (c) carries out global drug development and research in a closely integrated network including the U.S.; and (d) earns substantial revenues from the sales of its products, including Breo®, Anoro®, and Incruse®, in the U.S. On information and belief, GGL purposefully directs, directly or through its subsidiaries, including GSK, marketing and sales of pharmaceutical drug products, including Breo®, Anoro®, and Incruse®, throughout the U.S. Therefore, on information and belief, GGL has contacts with the U.S. sufficient to justify the application of U.S. law and to satisfy federal standards of forum selection.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

A. General Background

11. Vectura is the owner of the ’991 Patent, which issued on November 6, 2012 from United States Patent Application No. 12/767,530 (“the ’530 Application”).

12. GGL is identified in the Federal Food and Drug Administration ("FDA") "Orange Book" as the New Drug Application ("NDA") applicant for Breo®.

13. GSK is identified in the FDA Orange Book as the NDA applicant for Anoro®.

14. "Glaxo Grp England" is identified in the FDA Orange Book as the NDA applicant for Incruse®.

15. On information and belief, "Glaxo Grp England" is GGL.

16. Correspondence between the FDA and Glaxo concerning Breo®, Anoro®, and Incruse® is directed to and from GSK.

17. On information and belief, GSK and GGL have cooperated together in obtaining FDA approval of Breo®, Anoro®, and Incruse® and cooperate together to market and sell Breo®, Anoro®, and Incruse®.

18. Glaxo makes, uses, offers to sell, and/or sells Breo®, Anoro®, and Incruse® within the United States, thereby infringing at least claims 1-5, 7 and 9 of the '991 Patent.

B. Breo®, Anoro®, and Incruse® Infringe the '991 Patent

1. The '991 Patent

19. The '991 Patent is titled *Method of Making Particles for Use in a Pharmaceutical Composition*. The Abstract of the '991 Patent states that:

> The invention relates to a method for making composite active particles for use in a pharmaceutical composition for pulmonary administration, the method comprising a milling step in which particles of active material are milled in the presence of particles of an additive material which is suitable for the promotion of the dispersal of the composite active particles upon actuation of an inhaler. The invention also relates to compositions for inhalation prepared by the method.

(Ex. A, '991 Patent, Abstract, emphasis added.)

20. The ’991 Patent discloses and claims such compositions, with claim 1 reading as follows:

> 1. Composite active particles for use in a pharmaceutical composition for pulmonary administration, each composite active particle comprising
>
> a particle of active material and particulate additive material on the surface of that particle of active material,
>
> wherein the composite active particles have a mass median aerodynamic diameter of not more than 10 μm,
>
> and wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device.

(Ex. A, ’991 Patent, claim 1, line breaks added for readability.)

21. The remaining claims of the ’991 Patent are dependent claims further specifying the identity of the “additive material” (claims 2 and 3), the “mass median aerodynamic diameter” of the active particles (claim 4), the identity of the “active material” (claims 5-6), and claiming pharmaceutical compositions comprising the “composite active particles” of claim 1 (claims 7-10.)

22. Upon information and belief, Glaxo was aware of the ’991 Patent shortly after it issued, and engaged in conversations with Vectura concerning the ’991 Patent prior to the filing of this lawsuit.

2. <u>Breo®</u>

23. On information and belief, Breo® satisfies each and every limitation of at least claims 1-5, 7, and 9 of the ’991 Patent either literally or under the doctrine of equivalents.

24. On information and belief, as specified in all of claims 1-5, 7, and 9 of the ’991 Patent, Breo® contains “composite active particles for use in a pharmaceutical composition for

pulmonary administration, each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material, wherein the composite active particles have a mass median aerodynamic diameter of not more than 10 μm, and wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device."

25. Specifically, Breo® contains composite active particles comprising particles of vilanterol, an active material, and magnesium stearate, a particulate additive material, on the surface of the vilanterol particles. Claims 1, 4, 5, 7, and 9 specify an "additive material" generally, while claim 2 specifies that the "additive material" includes a "metal stearate", and claim 3 specifies that the metal stearate is magnesium stearate.

26. On information and belief, as specified in claims 1-5, 7, and 9 of the '991 Patent, Breo® contains composite active particles having a mass median aerodynamic diameter of not more than 10 μm (claims 1-3, 5, 7, and 9) and not more than 5 μm (claim 4). Specifically, Breo® contains composite active particles having a mass median aerodynamic diameter of between 3 and 4μm.

27. On information and belief, as specified in claims 1-5, 7, and 9 of the '991 Patent, "the additive material" in Breo® "promotes the dispersion of the composite active particles upon actuation of a delivery device." Specifically, magnesium stearate in Breo® promotes dispersion of vilanterol/magnesium stearate composite active particles upon actuation of a delivery device, namely the Ellipta® delivery device, which is a dry powder inhaler (claim 9). Breo® is a pharmaceutical composition, as specified in claim 7.

28. On information and belief, as specified in claim 5, the active material in Breo® comprises a β_2-agonist, vilanterol.

3. Anoro®

29. On information and belief, Anoro® satisfies each and every limitation of claims 1-5, 7, and 9 of the '991 Patent either literally or under the doctrine of equivalents.

30. On information and belief, as specified in all of claims 1-5, 7, and 9 of the '991 Patent, Anoro® contains "composite active particles for use in a pharmaceutical composition for pulmonary administration, each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material, wherein the composite active particles have a mass median aerodynamic diameter of not more than 10 μm, and wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device."

31. Specifically, Anoro® contains composite active particles comprising particles of vilanterol and particles of umeclidinium, which are active materials, and magnesium stearate, a particulate additive material, on the surface of the vilanterol and umeclidinium particles. Claims 1, 4, 5, 7, and 9 specify an "additive material" generally, while claim 2 specifies that the "additive material" includes a "metal stearate", and claim 3 specifies that the metal stearate is magnesium stearate.

32. On information and belief, as specified in all of claims 1-5, 7, and 9 of the '991 Patent, Anoro® contains composite active particles having a mass median aerodynamic diameter of not more than 10 μm (claims 1-3, 5, 7, and 9) and not more than 5 μm (claim 4). Specifically, Anoro® contains composite active particles having a mass median aerodynamic diameter of between 3 and 4μm.

33. On information and belief, as specified in all of claims 1-5, 7, and 9 of the '991 Patent, "the additive material" in Anoro® "promotes the dispersion of the composite active

particles upon actuation of a delivery device." Specifically, magnesium stearate in Anoro® promotes dispersion of vilanterol/magnesium stearate composite active particles and/or umeclidinium/magnesium stearate composite active particles upon actuation of a delivery device, namely the Ellipta® delivery device, which is a dry powder inhaler (claim 9). Anoro® is a pharmaceutical composition, as specified in claim 7.

34. On information and belief, as specified in claim 5, the active material in Anoro® comprises a β_2-agonist, vilanterol.

4. Incruse®

35. On information and belief, Incruse® satisfies each and every limitation of claims 1-4, 7, and 9 of the '991 Patent either literally or under the doctrine of equivalents.

36. On information and belief, as specified in all of claims 1-4, 7, and 9 of the '991 Patent, Incruse® contains "composite active particles for use in a pharmaceutical composition for pulmonary administration, each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material, wherein the composite active particles have a mass median aerodynamic diameter of not more than 10 μm, and wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device."

37. Specifically, Incruse® contains composite active particles comprising particles of umeclidinium, an active material, and magnesium stearate, a particulate additive material, on the surface of the umeclidinium particles. Claims 1, 4, 7, and 9 specify an "additive material" generally, while claim 2 specifies that the "additive material" includes a "metal stearate", and claim 3 specifies that the metal stearate is magnesium stearate.

38. On information and belief, as specified in all of claims 1-4, 7, and 9 of the '991 Patent, Incruse® contains composite active particles having a mass median aerodynamic diameter of not more than 10 μm (claims 1-3, 7, and 9) and not more than 5 μm (claim 4). Specifically, Incruse® contains composite active particles having a mass median aerodynamic diameter of between 3 and 4μm.

39. On information and belief, as specified in all of claims 1-4, 7, and 9 of the '991 Patent, "the additive material" in Incruse® "promotes the dispersion of the composite active particles upon actuation of a delivery device." Specifically, magnesium stearate in Incruse® promotes dispersion of umeclidinium/magnesium stearate composite active particles upon actuation of a delivery device, namely the Ellipta® delivery device, which is a dry powder inhaler (claim 9). Incruse® is a pharmaceutical composition, as specified in claim 7.

COUNT I

Infringement of the '991 Patent -- Breo®

40. Plaintiffs incorporate each of the preceding paragraphs 11 to 28 as if fully set forth herein.

41. For the reasons set forth in detail above, Glaxo's manufacture, use, offer for sale, sale, and/or importation of Breo® constitutes infringement of at least claims 1-5, 7, and 9 of the '991 Patent under 35 U.S.C. §§ 271(a) and 271(b).

42. Glaxo is aware of the existence of the '991 Patent and knows that its manufacture, use, offer for sale, sale, and/or importation of Breo® without a license infringes of one or more claims of the '991 Patent. This is an exceptional case.

COUNT II

Infringement of the ’991 Patent -- Anoro®

43. Plaintiffs incorporate each of the preceding paragraphs 11 to 22 and 29 to 34 as if fully set forth herein.

44. For the reasons set forth in detail above, Glaxo’s manufacture, use, offer for sale, sale, and/or importation of Anoro® constitutes infringement of at least claims 1-5, 7, and 9 of the ’991 Patent under 35 U.S.C. §§ 271(a) and 271(b).

45. Glaxo is aware of the existence of the ’991 Patent and knows that its manufacture, use, offer for sale, sale, and/or importation of Anoro® without a license infringes of one or more claims of the ’991 Patent. This is an exceptional case.

COUNT III

Infringement of the ’991 Patent -- Incruse®

46. Plaintiffs incorporate each of the preceding paragraphs 11 to 22 and 35 to 39 as if fully set forth herein.

47. For the reasons set forth in detail above, Glaxo’s manufacture, use, offer for sale, sale, and/or importation of Incruse® constitutes infringement of claims 1-4, 7, and 9 of the ’991 Patent under 35 U.S.C. §§ 271(a) and 271(b).

48. Glaxo is aware of the existence of the ’991 Patent and knows that its manufacture, use, offer for sale, sale, and/or importation of Incruse® without a license infringes of one or more claims of the ’991 Patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. that judgment be entered that Glaxo has infringed and is infringing the '991 Patent through the manufacture, use, offer for sale, sale, and/or importation of Breo®;

B. that judgment be entered that Glaxo has infringed and is infringing the '991 Patent through the manufacture, use, offer for sale, sale, and/or importation of Anoro®;

C. that judgment be entered that Glaxo has infringed and is infringing the '991 Patent through the manufacture, use, offer for sale, sale, and/or importation of Incruse®;

D. that judgment be entered that Glaxo's infringement has been willful;

E. that damages or other monetary relief be awarded to Vectura as appropriate with respect to Glaxo's past infringement and any continuing or future infringement of the '991 Patent;

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

G. costs and expenses in this action; and

H. such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Vectura hereby demands trial by jury on all claims and issues so triable.

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