IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA RESPIRATORY, LLC, NORTON (WATERFORD) LIMITED, and NORTON HEALTHCARE LIMITED, Plaintiffs, v. PERRIGO PHARMACEUTICALS CO., PERRIGO CO., and CATALENT PHARMA SOLUTIONS, LLC Defendants.	Civil Action No. 12-_____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Teva Respiratory, LLC, Norton (Waterford) Limited, and Norton Healthcare Limited, hereby demand a trial by jury on all issues so triable and for their complaint state as follows:

1. Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Teva Respiratory, LLC, Norton (Waterford) Limited, and Norton Healthcare Limited (collectively, "Teva") bring this action for patent infringement against Perrigo Co., Perrigo Pharmaceuticals Co. (collectively, "Perrigo") and Catalent Pharma Solutions, LLC ("Catalent", and collectively with Perrigo, "Defendants") for infringement of United States Patent Nos. 7,105,152 ("the '152 patent") and 7,566,445 ("the '445 patent").

THE PARTIES

2. Teva Branded Pharmaceutical Products R&D, Inc. is a Delaware corporation with its principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044.

3. Teva Respiratory, LLC is a Florida limited liability company with its principal place of business at 425 Privet Road, Horsham, Pennsylvania 19044.

4. Norton (Waterford) Limited is a private limited company trading as Teva Pharmaceuticals Ireland (Company No 100363) incorporated under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford, Republic of Ireland.

5. Norton Healthcare Limited is a private limited company trading as Ivax Pharmaceuticals Ireland or Teva Pharmaceuticals Ireland (Company No. 00947980) incorporated under the laws of England and having its registered office at Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX.

6. Upon information and belief, Perrigo Co. is a global healthcare supplier that develops, manufactures and distributes across the United States over-the-counter and generic prescription pharmaceuticals, nutritional products, active pharmaceutical ingredients and pharmaceutical and medical diagnostic products.

7. Upon information and belief, Perrigo Co. is a Michigan corporation having its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

8. Upon information and belief, Perrigo Co. is doing business in the State of Delaware, including in this Judicial District.

9. Perrigo Co. has engaged in continuous and systematic contacts with the State of Delaware and purposefully availed itself of this forum by, among other things, shipping to,

using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Delaware including in this Judicial District and deriving revenue from such activities. Perrigo Co.'s products are sold by mass merchandisers, food stores and drug stores throughout the United States, including within this Judicial district. On information and belief, Perrigo Co. derives substantial revenue from the sales of those products in this Judicial District.

10. Upon information and belief, Perrigo Co. has been sued for patent infringement in this Judicial District (e.g., C.A. Nos. 99-813, 04-107 and 09-167, 11-733) and has admitted that it is subject to personal jurisdiction in this Court.

11. Upon information and belief, Perrigo Pharmaceuticals Co. is a Michigan corporation having its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

12. Upon information and belief, Perrigo Pharmaceuticals Co. is a wholly owned subsidiary of Perrigo Co., and together these companies function as a fully-integrated corporate entity.

13. Perrigo Pharmaceuticals Co. is registered to distribute drugs in the State of Delaware, pursuant to 24 Del. C. § 2540, as a licensed "Pharmacy – Wholesale" (License Nos. A4-0001254 and A4-0001316).

14. Upon information and belief, Perrigo Pharmaceuticals Co. is doing business in the State of Delaware, including in this Judicial District.

15. Upon information and belief, Perrigo Pharmaceuticals Co. has engaged in continuous and systematic contacts with the State of Delaware and purposefully availed itself of this forum by, among other things, shipping to, using, offering to sell or selling, or causing others

to use, offer to sell, or sell, pharmaceutical products in the State of Delaware including in this Judicial District and deriving revenue from such activities. On information and belief, Perrigo Pharmaceuticals Co. derives substantial revenue from the sales of those products in this Judicial District.

16. Upon information and belief, Catalent Pharma Solutions, LLC ("Catalent") partners with pharmaceutical companies to develop and manufacture pharmaceutical products, including inhalation aerosol products.

17. Catalent is a Delaware limited liability company with its principal place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873.

18. Upon information and belief, Catalent is doing business in the State of Delaware, including in this Judicial District.

19. Upon information and belief, Catalent has engaged in continuous and systematic contacts with the State of Delaware and purposefully availed itself of this forum by, among other things, shipping to, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Delaware including in this Judicial District and deriving revenue from such activities. On information and belief, Catalent derives substantial revenue from the sales of those products in this Judicial District.

20. Catalent is registered to do business in Delaware, and has designated Corporation Service Company at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808 for receipt of service.

JURISDICTION AND VENUE

21. This action for patent infringement arises under 35 U.S.C. § 271(e).

22. This Court has jurisdiction over Counts I-IV of this action pursuant to 28 U.S.C. § 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

23. Venue is proper in this Judicial District under 28 U.S.C. § 1400(b) and § 1391.

24. This Court has personal jurisdiction over Perrigo Co., Perrigo Pharmaceuticals Co., and Catalent at least because they have consented to personal jurisdiction in Delaware and because their activities satisfy the Delaware long arm-statute, 10 Del. Code. § 3104.

BACKGROUND

The Patents-in-Suit

25. United States Patent No. 7,566,445 ("the '445 patent"), entitled "Medicinal Aerosols and Methods of Delivery Thereof," was duly and legally issued to Norton Healthcare Limited on July 28, 2009, and expires on June 4, 2017. A true and correct copy of the '445 patent is attached as Exhibit A. Since its date of issue, Norton Healthcare Limited has been and still is the assignee of that patent.

26. Teva Branded Pharmaceutical Products R&D, Inc., Teva Respiratory, LLC, and Norton (Waterford) Limited are co-exclusive licensees of the '445 patent and have the right to enforce the '445 patent against Perrigo and Catalent.

27. United States Patent No. 7,105,152 (the "'152 patent"), entitled "Suspension Aerosol Formulations" was duly and legally issued to 3M Innovative Properties Corp. on September 12, 2006, and expires on September 12, 2023. A true and correct copy of the '152 patent is attached as Exhibit B.

28. Norton (Waterford) Limited is the assignee of the '152 patent.

29. Teva Branded Pharmaceutical Products R&D, Inc. and Teva Respiratory, LLC are co-exclusive licensees of the ’152 patent and have the right to enforce the ’152 patent against Perrigo and Catalent.

Teva’s ProAir® HFA product

30. Teva Branded Pharmaceutical Products R&D, Inc. is the holder of NDA No. 21-457, ProAir® HFA (albuterol sulfate) Inhalation Aerosol. Teva’s ProAir® HFA (albuterol sulfate) inhaler is approved by the FDA for the treatment or prevention of bronchospasm with reversible obstructive airway disease in patients 4 years of age and older and for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

31. Teva’s innovative ProAir® HFA product is a pressurized metered-dose inhaler with albuterol sulfate as the active ingredient (0.09 mg/inhalation), manufactured by Norton (Waterford) Limited (trading as Ivax Pharmaceuticals Ireland) and marketed and sold in the United States by Teva Respiratory, LLC.

32. The FDA’s *Orange Book* lists the ’445 and ’152 patents as relating to Teva’s ProAir® HFA (albuterol sulfate) product.

Perrigo’s ANDA No. 203760

33. Upon information and belief, Perrigo Pharmaceuticals Co. filed with the FDA an Abbreviated New Drug Application (“ANDA”) pursuant to 21 U.S.C. § 355(j), to obtain approval for Albuterol Sulfate Inhalation Aerosol, 0.09 mg per actuation (“Albuterol ANDA Product”), purported to be generic to Teva’s ProAir® HFA product.

34. Upon information and belief, Perrigo Pharmaceuticals Co. filed ANDA No. 203760 in order to obtain approval to market its Albuterol ANDA Product before the expiration of the ’152 and ’445 patents (collectively, “the patents-in-suit”).

35. Upon information and belief, Perrigo Pharmaceuticals Co. also filed with the FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of its Albuterol ANDA Product.

36. Perrigo Pharmaceuticals Co. caused to be sent to Teva a letter ("the Notice Letter"), dated July 24, 2012, notifying them that it had filed its ANDA No. 203760, Albuterol Sulfate Inhalation Aerosol, 0.09 mg per actuation, and providing information to Teva pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

37. Teva received the Notice Letter no earlier than on or about July 25, 2012.

38. Teva has filed this lawsuit within the 45-day period pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

39. Upon information and belief, Perrigo Co. and Catalent worked in active concert and participation with Perrigo Pharmaceuticals Co. to develop and manufacture the Albuterol ANDA Product and to prepare ANDA No. 203760.

40. Upon information and belief, Catalent intends to manufacture the Albuterol ANDA Product in the United States upon approval by the FDA.

41. Upon information and belief, Perrigo Co. intends to market, sell, offer for sale, and distribute the Albuterol ANDA Product in the Unites States upon approval by the FDA.

42. Upon information and belief, Defendants had knowledge and were aware of the patents-in-suit before the filing of ANDA No. 203760.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 7,566,445

43. The allegations of the proceeding paragraphs 1-42 are realleged and incorporated herein by reference.

44. Under 35 U.S.C. § 271(e)(2)(A), Perrigo Pharmaceuticals Co.'s submission to the FDA of its ANDA No. 203760 to obtain approval for its Albuterol ANDA Product before the expiration of the '445 patent constitutes an act of infringement, and if approved, the commercial manufacture, use, offer to sell, sale, or importation of its Albuterol ANDA Product would infringe one or more claims of the '445 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

45. Upon information and belief, Perrigo Co. and Catalent have, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced Perrigo Pharmaceutical Co.'s filing of ANDA No. 203760 for its generic Albuterol ANDA Product, and in the preparation to sell, in the United States, Albuterol ANDA Product.

46. Upon information and belief, Perrigo and Catalent have knowingly and willfully infringed the '445 patent.

47. Teva will be irreparably harmed if Perrigo and Catalent are not enjoined from infringing the '445 patent.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 7,105,152

48. The allegations of the proceeding paragraphs 1-47 are realleged and incorporated herein by reference.

49. Under 35 U.S.C. § 271(e)(2)(A), Perrigo Pharmaceutical Co.'s submission to the FDA of its ANDA No. 203760 to obtain approval for its Albuterol ANDA Product before the expiration of the '152 patent constitutes an act of infringement, and if approved, the commercial manufacture use, offer to sell, sale, or importation of the Albuterol ANDA Product would infringe one or more claims of the '445 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

50. Upon information and belief, Perrigo Co. and Catalent have, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced Perrigo

Pharmaceutical Co.'s filing of ANDA No. 203760 for its generic Albuterol ANDA Product, and in the preparation to sell, in the United States, its Albuterol ANDA Product.

51. Upon information and belief, Perrigo and Catalent have knowingly and willfully infringed the '152 patent.

52. Teva will be irreparably harmed if Perrigo and Catalent are not enjoined from infringing the '152 patent.

COUNT III FOR DECLARATORY JUDGMENT
OF INFRINGEMENT OF U.S. PATENT NO. 7,566,445

53. The allegations of the proceeding paragraphs 1-52 are realleged and incorporated herein by reference.

54. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing the Albuterol ANDA Product soon after FDA approval.

55. Such conduct will constitute direct infringement of one or more claims of the '445 patent under 35 U.S.C. § 271(a), inducement of infringement of the '445 patent under 35 U.S.C.§ 271(b), and contributory infringement of the '445 patent under 35 U.S.C. § 271(c).

56. Defendants' infringing patent activity complained of herein is imminent and will begin following FDA approval of the ANDA.

57. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the '445 patent. Defendants' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

58. Upon information and belief, Perrigo and Catalent will knowingly and willfully infringe the '445 patent.

59. Teva will be irreparably harmed if Perrigo and Catalent are not enjoined from infringing the ’445 patent.

COUNT IV FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,105,152

60. The allegations of the proceeding paragraphs 1-59 are realleged and incorporated herein by reference.

61. Upon information and belief, Defendants plan to begin manufacturing, marketing, selling, offering to sell and/or importing Albuterol ANDA Product soon after FDA approval.

62. Such conduct will constitute direct infringement of one or more claims of the ’152 patent under 35 U.S.C. § 271(a), inducement of infringement of the ’152 patent under 35 U.S.C.§ 271(b), and contributory infringement of the ’152 patent under 35 U.S.C. § 271(c).

63. Defendants’ infringing patent activity complained of herein is imminent and will begin following FDA approval of the ANDA.

64. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants as to liability for the infringement of the ’152 patent. Defendants’ actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants’ threatened imminent actions.

65. Upon information and belief, Perrigo and Catalent will knowingly and willfully infringe the ’152 patent.

66. Teva will be irreparably harmed if Perrigo and Catalent are not enjoined from infringing the ’152 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

(a) declaring that the ’445 patent is valid and enforceable;

(b) declaring that Defendants have infringed one or more claims of the ’445 patent by the filing of ANDA No. 203760, and would infringe one or more claims of the ’445 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Perrigo’s generic Albuterol ANDA Product prior to the expiration of the ’445 patent and any regulatory exclusivities;

(c) declaring that that ’152 patent is valid and enforceable;

(d) declaring that Defendants have infringed one or more claims of the ’152 patent by the filing of ANDA No. 203769, and would infringe one or more claims of the ’152 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Perrigo’s generic Albuterol ANDA Product prior to the expiration of the ’152 patent patent and any regulatory exclusivities;

(e) ordering that the effective date of the FDA approval of Perrigo’s generic Albuterol ANDA Product shall not be before the expiration of the patents-in-suit, in accordance with 35 U.S.C. § 271(e)(4)(A);

(f) enjoining Defendants from the commercial manufacture, use, offer to sell, sale, or importation of Perrigo’s generic Albuterol ANDA Product, in accordance with 35 U.S.C. § 271(e)(4)(B);

(g) awarding Plaintiffs damages or other monetary relief in accordance with 35 U.S.C. § 271(e)(4)(C) to compensate Plaintiffs for any and all commercial manufacture, use, offer

to sell, sale, or importation of Perrigo's generic Albuterol ANDA Product prior to the expiration of the patents-in-suit;

(h) declaring this to be an exceptional case and awarding Plaintiffs attorneys' fees under 35 U.S.C. §§ 285 and 271(e)(4);

(i) in the event that Perrigo obtains final approval for Perrigo's generic Albuterol ANDA Product prior to judgment being entered in this action, enjoining, including preliminarily enjoining, Defendants from the commercial manufacture, use, offer to sell, sale, or importation of Perrigo's generic Albuterol ANDA Product in the United States before the expiration of the patents-in-suit in accordance with 35 U.S.C. § 283; and

(j) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, Plaintiffs demand a jury trial on all issues so triable.

Respectfully submitted,

/s/ John W. Shaw

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