IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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| TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., TEVA RESPIRATORY, LLC, NORTON (WATERFORD) LIMITED, and NORTON HEALTHCARE LIMITED, | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| LUPIN ATLANTIS HOLDINGS SA, LUPIN PHARMACEUTICALS, INC., and LUPIN LTD., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Teva Respiratory, LLC, Norton (Waterford) Limited, and Norton Healthcare Limited, hereby 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" or "Plaintiffs") bring this action for patent infringement against Lupin Alantis Holdings SA, Lupin Pharmaceuticals, Inc., and Lupin Ltd. (collectively "Lupin" or "Defendants") for infringement of United States Patent Nos. 7,105,152 ("the '152 patent"), 8,132,712 ("the '712 patent"), and 9,463,289 ("the '289 patent").

## THE PARTIES

2. Teva Branded Pharmaceutical Products R&D, Inc. is a company organized under the laws of the State of Delaware with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

3. Teva Respiratory, LLC is a limited liability company organized under the laws of the State of Florida with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355.

4. Norton (Waterford) Limited is a private limited company trading as Ivax Pharmaceuticals Ireland or as Teva Pharmaceuticals Ireland (Company No. 100363) organized 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 UK or Teva Runcorn (Company No. 0947980) organized 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, Lupin Atlantis Holdings SA is a company organized under the laws of Switzerland and having its principle place of business at Mulentalstrasse 2, 8200 Schaffhuasen, Switzerland.

7. Upon information and belief, Lupin Atlantis Holdings SA is a subsidiary of Lupin Ltd.

8. Upon information and belief, Lupin Ltd. is a company organized under the laws of India and having its principle place of business at Laxmi Towers, B Wing 5th Floor Bandra Kurla Complex Bandra (East), Mumbai, Maharashtra, 40005, India.

9. Upon information and belief, Lupin Pharmaceuticals, Inc. is a company organized under the laws of the State of Delaware and having its principle place of business at 111 South Calvert Street Harborplace Tower 21st Floor, Baltimore, MD, 21202.

10. Upon information and belief, Lupin Pharmaceuticals Inc. is a subsidiary of Lupin Ltd.

## JURISDICTION AND VENUE

11. This action for patent infringement arises under 35 U.S.C. § 271.

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

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

**Personal Jurisdiction Over Lupin Pharmaceuticals, Inc.**

14. Upon information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals Inc.

15. Upon information and belief, Lupin Pharmaceuticals Inc. is incorporated in the State of Delaware.

16. Upon information and belief, Lupin Pharmaceuticals, Inc. markets, distributes and/or sells generic drugs within the State of Delaware and throughout the United States.

17. Upon information and belief, Lupin Pharmaceuticals, Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of the State of Delaware rendering it at home in the State of Delaware.

18. Upon information and belief, Lupin Pharmaceuticals, Inc. routinely files Abbreviated New Drug Applications ("ANDAs") with the U.S. Food & Drug Administration

("FDA") and markets dozens of generic pharmaceutical products in the State of Delaware, including, *inter alia*, cefixime, desloratadine, meloxicam, pravastatin sodium, and rifampin.

19. Upon information and belief, Lupin Pharmaceuticals, Inc. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, *inter alia*, cefixime, desloratadine, meloxicam, pravastatin sodium, and rifampin.

20. Upon information and belief, Lupin Pharmaceuticals, Inc. has committed or will imminently commit acts that aid, abet, contribute to and/or constitute tortious patent infringement that will harm and injure Teva, which manufactures PROAIR® HFA (albuterol sulfate) Inhalation Aerosol for sale and use throughout the United States, including the State of Delaware.

21. Teva sells PROAIR® HFA (albuterol sulfate) Inhalation Aerosol in the State of Delaware.

22. Upon information and belief, Lupin Pharmaceuticals, Inc. has applied for FDA approval to market and sell a generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol throughout the United States, including in the State of Delaware.

23. Upon information and belief, following any FDA approval of Lupin's ANDA, Lupin Pharmaceuticals, Inc., Lupin Atlantis Holdings SA, and Lupin Ltd. will work in concert with one another to make, use, offer to sell, and sell a generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol throughout the United States, including in the State of Delaware.

24. Upon information and belief, as a result of Lupin's marketing, selling, or offering for sale of its generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol in the

State of Delaware, Teva will lose sales of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol and be injured in the State of Delaware.

25. Upon information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because it previously has been sued in this district and did not challenge this Court's assertion of personal jurisdiction over it, and/or availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes. *See Unimed Pharmaceuticals LLC, et al. v. Lupin Atlantis Holdings SA, et al.*, C.A. No. 15-cv-00904; *Sanofi, et al. v. Lupin Atlantis Holdings SA, et al.*, C.A. No. 15-cv-00415-RGA (D. Del.); *Vanda Pharmaceuticals Inc. v. Lupin Ltd., et al.*, C.A. No. 15-01073-GMS (D. Del.); *iCeutica Pty. Ltd. v. Lupin Ltd.*, C.A. No. 14-1515-SLR-SRF (D. Del.); *Forest Labs., LLC v. Lupin Ltd.*, C.A. No. 14-1058-LPS (D. Del.); *VIIV Healthcare UK Ltd. v. Lupin Ltd.,* C.A. No. 14-0369-LPS (D. Del.).

26. Upon information and belief, the exercise of personal jurisdiction over Lupin Pharmaceuticals, Inc. in this forum is not unreasonable.

27. Upon information and belief, this Court has general and specific personal jurisdiction over Lupin Pharmaceuticals, Inc. for the reasons stated herein, including, *inter alia*, Lupin Pharmaceuticals, Inc. is incorporated in this forum, its activities in this forum, its activities directed at this forum, and its significant contacts with this forum, all of which render Lupin Pharmaceuticals, Inc. at home in this forum.

**Personal Jurisdiction Over Lupin Atlantis Holdings SA**

28. Upon information and belief, this Court has personal jurisdiction over Lupin Atlantis Holdings SA.

29. Upon information and belief, Lupin Atlantis Holdings SA is partnering with Lupin Pharmaceuticals Inc. and Lupin Ltd. to attempt to bring a generic PROAIR® HFA (albuterol sulfate) Inhalation Aerosol to market in the United States, including in the State of Delaware.

30. Upon information and belief, Lupin Atlantis Holdings SA collaborated and/or acted in concert with Lupin Pharmaceuticals Inc. and Lupin Ltd. to apply for FDA approval to market and sell a generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol throughout the United States, including in the State of Delaware.

31. Upon information and belief, Lupin Atlantis Holdings SA (through its partners Lupin Pharmaceuticals, Inc. and Lupin Ltd.) markets, distributes and/or sells generic drugs within the State of Delaware and throughout the United States.

32. Upon information and belief, Lupin Atlantis Holdings SA has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of the State of Delaware, rendering it at home in the State of Delaware.

33. Upon information and belief, Lupin Atlantis Holdings SA routinely files ANDAs with the FDA and markets dozens of generic pharmaceutical products in the State of Delaware, including, *inter alia*, desoximetasone, ethinyl estradiol norethindrone acetate, fenofibrate, and triamcinolone acetate.

34. Upon information and belief, Lupin Atlantis Holdings SA has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, *inter alia*, desoximetasone, ethinyl estradiol norethindrone acetate, fenofibrate, and triamcinolone acetate.

35. Upon information and belief, Lupin Atlantis Holdings SA has committed or will imminently commit acts that aid, abet, contribute to and/or constitute tortious patent infringement that will harm and injure Teva, which manufactures PROAIR® HFA (albuterol sulfate) Inhalation Aerosol for sale and use throughout the United States, including in the State of Delaware.

36. Teva sells PROAIR® HFA (albuterol sulfate) Inhalation Aerosol in the State of Delaware.

37. Upon information and belief, Lupin has applied for FDA approval to market and sell a generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol throughout the United States, including in the State Delaware.

38. Upon information and belief, following any FDA approval of Lupin's ANDA, Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Lupin Ltd. will work in concert with one another to make, use, offer to sell, and sell a generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol throughout the United States, including in the State of Delaware.

39. Upon information and belief, as a result of Lupin's marketing, selling, or offering for sale of its generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol in the State of Delaware, Teva will lose sales of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol and be injured in the State of Delaware.

40. This Court also has personal jurisdiction over Lupin Atlantis Holdings SA under Federal Rule of Civil Procedure 4(k)(2).

41. Upon information and belief, this Court has personal jurisdiction over Lupin Atlantis Holdings SA because it previously has brought suit in this district, has been sued in

this district and did not challenge this Court's assertion of personal jurisdiction over it, and/or availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes. *See Lupin Atlantis Holdings SA v. Ranbaxy Laboratories, Ltd., et al.*, C.A. No. 10-0659-SLR (D. Del.); *Lupin Atlantis Holdings SA v. Apotex Inc., et al.*, C.A. No. 11-0234-LPS (D. Del.); *Lupin Atlantis Holdings SA v. InvaGen Pharmaceuticals Inc., et al.*, C.A. No. 16-0708-SLR-SRF (D. Del.); *Unimed Pharmacetuicals LLC, et al. v. Lupin Atlantis Holdings SA, et al.*, C.A. No. 15-0904; *Sanofi, et al. v. Lupin Atlantis Holdings SA, et al.*, C.A. No. 15-0415-RGA (D. Del.).

42. Upon information and belief, the exercise of personal jurisdiction over Lupin Atlantis Holdings SA in this forum is not unreasonable.

43. Upon information and belief, this Court has general and specific personal jurisdiction over Lupin Atlantis Holdings SA for the reasons stated herein, including, *inter alia*, Lupin Atlantis Holdings SA's activities in this forum, activities directed at this forum, and significant contacts with this forum, all of which render Lupin Atlantis Holdings SA at home in this forum.

**Personal Jurisdiction Over Lupin Ltd.**

44. Upon information and belief, this Court has personal jurisdiction over Lupin Ltd.

45. Upon information and belief, Lupin Ltd. is partnering with Lupin Pharmaceuticals, Inc. and Lupin Atlantis Holdings SA to attempt to bring a generic PROAIR® HFA (albuterol sulfate) Inhalation Aerosol to market in the United States, including within the State of Delaware.

46. Upon information and belief, Lupin Ltd. collaborated and/or acted in concert with Lupin Pharmaceuticals, Inc. and Lupin Atlantis Holdings SA to apply for FDA approval to

market and sell a generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol throughout the United States, including within the State of Delaware.

47. Upon information and belief, Lupin Ltd. (through its partners Lupin Pharmaceuticals, Inc. and Lupin Atlantis Holdings SA) markets, distributes and/or sells generic drugs within the State of Delaware and throughout the United States.

48. Upon information and belief, Lupin Ltd. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of the State of Delaware, rendering it at home in the State of Delaware.

49. Upon information and belief, Lupin Ltd. routinely files ANDAs with the FDA and markets dozens of generic pharmaceutical products in the State of Delaware, including, *inter alia*, gatifloxacin, abacavir sulfate/lamivudine/zidovudine, and duloxetine.

50. Upon information and belief, Lupin Ltd. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, *inter alia*, gatifloxacin, abacavir sulfate/lamivudine/zidovudine, and duloxetine.

51. Upon information and belief, Lupin Ltd. has committed or will imminently commit acts that aid, abet, contribute to and/or constitute tortious patent infringement that will harm and injure Teva, which manufactures PROAIR® HFA (albuterol sulfate) Inhalation Aerosol for sale and use throughout the United States, including the State of Delaware.

52. Teva sells PROAIR® HFA (albuterol sulfate) Inhalation Aerosol in the State of Delaware.

53. Upon information and belief, Lupin has applied for FDA approval to market and sell a generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol throughout the United States, including within the State of Delaware.

54. Upon information and belief, following any FDA approval of Lupin's ANDA, Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Lupin Ltd. will work in concert with one another to make, use, offer to sell, and sell a generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol throughout the United States, including within the State of Delaware.

55. Upon information and belief, as a result of Lupin's marketing, selling, or offering for sale of its generic version of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol in the State of Delaware, Teva will lose sales of PROAIR® HFA (albuterol sulfate) Inhalation Aerosol and be injured in the State of Delaware.

56. This Court also has personal jurisdiction over Lupin Ltd. under Federal Rule of Civil Procedure 4(k)(2).

57. Upon information and belief, this Court has personal jurisdiction over Lupin Ltd. because it previously has been sued in this district and did not challenge this Court's assertion of personal jurisdiction over it, and/or availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes. *See Unimed Pharmacetuicals LLC, et al. v. Lupin Atlantis Holdings SA, et al.*, C.A. No. 15-0904; *Sanofi, et al. v. Lupin Atlantis Holdings SA, et al.*, C.A. No. 15-0415-RGA (D. Del.); *Vanda Pharmaceuticals Inc. v. Lupin Ltd., et al.*, C.A. No. 15-1073-GMS (D. Del.); *iCeutica Pty. Ltd. v. Lupin Ltd.*, C.A. No. 14-1515-SLR-SRF (D. Del.);

*Forest Labs., LLC v. Lupin Ltd.*, C.A. No. 14-1058-LPS (D. Del.); *VIIV Healthcare UK Ltd. v. Lupin Ltd.*, C.A. No. 14-0369-LPS (D. Del.).

58. Upon information and belief, the exercise of personal jurisdiction over Lupin Ltd. in this forum is not unreasonable.

59. Upon information and belief, this Court has personal jurisdiction over Lupin Ltd. for the reasons stated herein, including, *inter alia*, Lupin Ltd.'s activities in this forum, activities directed at this forum, and significant contacts with this forum, all of which render Lupin Ltd. at home in this forum.

## BACKGROUND

### The '152 Patent

60. United States Patent No. 7,105,152, entitled "Suspension Aerosol Formulations" was duly and legally issued to 3M Innovative Properties Corp. on September 12, 2006, and expires on September 12, 2023.

61. Robert K. Shultz, David W. Schultz, and Robert A. Moris are named inventors of the '152 patent.

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

63. 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 Lupin.

64. A true and correct copy of the '152 patent is attached as Exhibit A.

**The ’712 Patent**

65. United States Patent No. 8,132,712, entitled “Metered-Dose Inhaler” was duly and legally issued to Ivax Pharmaceuticals Ireland (Norton (Waterford) Limited) on March 13, 2012, and expires on September 7, 2028.

66. Derek Fenlon is the named inventor of the ’712 patent.

67. Since its date of issue, Ivax Pharmaceuticals Ireland (Norton (Waterford) Limited) has been and still is the assignee of the ’712 patent.

68. A true and correct copy of the ’712 patent is attached as Exhibit B.

**The ’289 Patent**

69. United States Patent No. 9,463,289, entitled “Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof” was duly and legally issued to Ivax Pharmaceuticals Ireland, Norton(Waterford) Limited, and Teva Pharmaceuticals Ireland on October 11, 2016, and expires on May 18, 2031.

70. Declan Walsh, Derek Fenlon, Simon Kaar, Geert Hazenberg, Daniel Buck, Paul Clancy, Robert Charles Uschold, and Jeffrey A. Karg are named inventors of the ’289 patent.

71. Ivax Pharmaceuticals Ireland, Norton (Waterford) Limited, and Teva Pharmaceuticals Ireland are the assignees of the ’289 patent.

72. A true and correct copy of the ’289 patent is attached as Exhibit C.

**Teva’s PROAIR® HFA product**

73. 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.

74. Teva's innovative PROAIR® HFA product is a pressurized metered-dose inhaler with albuterol sulfate as the active ingredient (equivalent to 90 mcg of albuterol base), manufactured by Norton (Waterford) Limited (trading as Ivax Pharmaceuticals Ireland or Teva Pharmaceuticals Ireland) and marketed and sold in the United States by Teva Respiratory, LLC.

75. The FDA's *Orange Book* lists U.S. Patent No. 7,566,445, the '152, U.S. Patent No. 6,446,627, the '712, U.S. Patent No. 8,834,849, and the '289 patent as relating to Teva's PROAIR® HFA (albuterol sulfate) Inhalation Aerosol product.

**Lupin's ANDA No. 209954**

76. Upon information and belief, Lupin Atlantis Holding SA, through its authorized U.S. agent Lupin Pharmaceuticals, Inc., filed with FDA an ANDA pursuant to 21 U.S.C. § 355(j), to obtain approval for an Albuterol Sulfate Inhalation Aerosol, equivalent to 0.09 mg albuterol base per actuation ("Albuterol ANDA Product"), purported to be generic to Teva's PROAIR® HFA (albuterol sulfate) Inhalation Aerosol product.

77. Upon information and belief, Lupin Atlantis Holding SA, through its authorized U.S. agent Lupin Pharmaceuticals Inc., filed ANDA No. 209954 in order to obtain approval to market its Albuterol ANDA Product before the expiration of the '152, '712, and '289 patents (collectively, "the patents-in-suit").

78. Upon information and belief, Lupin Atlantis Holding SA, through its authorized U.S. agent Lupin Pharmaceuticals, Inc., also filed with 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 ("paragraph (IV) certification").

79. Lupin Atlantis Holding SA caused to be sent to Teva a letter ("the Notice Letter"), dated February 6, 2017, notifying Teva that it had filed its ANDA No. 209954, for an Albuterol Sulfate Inhalation Aerosol, equivalent to 0.09 mg albuterol base per actuation, with a paragraph (IV) certification, and providing information to Teva pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

80. Teva received the Notice Letter no earlier than on or about February 7, 2017.

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

82. Upon information and belief, Lupin Ltd., Lupin Atlantis Holdings SA, and Lupin Pharmaceuticals, Inc. worked in active concert and participation to develop and manufacture the Albuterol ANDA Product and to prepare and file ANDA No. 209954.

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

84. Upon information and belief, Lupin had knowledge and were aware of the patents-in-suit before the filing of ANDA No. 209954.

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

85. The allegations of the preceding paragraphs 1-84 are realleged and incorporated herein by reference.

86. Under 35 U.S.C. § 271(e)(2)(A), Lupin's submission to the FDA of its ANDA No. 209954 with a paragraph (IV) certification 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 ’152 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

87. Upon information and belief, Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Lupin Ltd. have, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced Lupin’s filing of ANDA No. 209954 for its generic Albuterol ANDA Product, and in the preparation to sell, in the United States, its Albuterol ANDA Product.

88. Upon information and belief, Lupin has knowingly and willfully infringed the ’152 patent.

89. Teva will be irreparably harmed if Lupin is not enjoined from infringing the ’152 patent.

**COUNT II FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 7,105,152**

90. The allegations of the preceding paragraphs 1-89 are realleged and incorporated herein by reference.

91. Upon information and belief, Lupin plans to begin manufacturing, marketing, selling, offering to sell and/or importing Albuterol ANDA Product soon after FDA approval.

92. 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).

93. Lupin’s infringing patent activity complained of herein is imminent and will begin following FDA approval of the ANDA.

94. 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. Lupin’s actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants’ threatened imminent actions.

95. Upon information and belief, Lupin will knowingly and willfully infringe the ’152 patent.

96. Teva will be irreparably harmed if Lupin is not enjoined from infringing the ’152 patent.

**COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,132,712**

97. The allegations of the preceding paragraphs 1-96 are realleged and incorporated herein by reference.

98. Under 35 U.S.C. § 271(e)(2)(A), Lupin’s submission to the FDA of its ANDA No. 209954 with a paragraph (IV) certification to obtain approval for its Albuterol ANDA Product before the expiration of the ’712 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 ’712 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

99. Upon information and belief, Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Lupin Ltd. have, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced Lupin’s filing of ANDA No. 209954 for its generic Albuterol ANDA Product, and in the preparation to sell, in the United States, its Albuterol ANDA Product.

100. Upon information and belief, Lupin has knowingly and willfully infringed the ’712 patent.

101. Teva will be irreparably harmed if Lupin is not enjoined from infringing the ’712 patent.

**COUNT IV FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 8,132,712**

102. The allegations of the preceding paragraphs 1-101 are realleged and incorporated herein by reference.

103. Upon information and belief, Lupin plans to begin manufacturing, marketing, selling, offering to sell and/or importing Albuterol ANDA Product soon after FDA approval.

104. Such conduct will constitute direct infringement of one or more claims of the '712 patent under 35 U.S.C. § 271(a), inducement of infringement of the '712 patent under 35 U.S.C.§ 271(b), and contributory infringement of the '712 patent under 35 U.S.C. § 271(c).

105. Lupin's infringing patent activity complained of herein is imminent and will begin following FDA approval of the ANDA.

106. 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 '712 patent. Lupin's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

107. Upon information and belief, Lupin will knowingly and willfully infringe the '712 patent.

108. Teva will be irreparably harmed if Lupin is not enjoined from infringing the '712 patent.

**COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 9,463,289**

109. The allegations of the preceding paragraphs 1-108 are realleged and incorporated herein by reference.

110. Under 35 U.S.C. § 271(e)(2)(A), Lupin's submission to the FDA of its ANDA No. 209954 with a paragraph (IV) certification to obtain approval for its Albuterol ANDA

Product before the expiration of the ’289 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 ’289 patent under at least sections (a)-(c) of 35 U.S.C. § 271.

111. Upon information and belief, Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Lupin Ltd. have, under 35 U.S.C. § 271(b), acted in concert, actively supported, participated in, encouraged, and/or induced Lupin’s filing of ANDA No. 209954 for its generic Albuterol ANDA Product, and in the preparation to sell, in the United States, its Albuterol ANDA Product.

112. Upon information and belief, Lupin has knowingly and willfully infringed the ’289 patent.

113. Teva will be irreparably harmed if Lupin is not enjoined from infringing the ’289 patent.

**COUNT VI FOR DECLARATORY JUDGMENT OF INFRINGMENT OF U.S. PATENT NO. 9,463,289**

114. The allegations of the preceding paragraphs 1-113 are realleged and incorporated herein by reference.

115. Upon information and belief, Lupin plans to begin manufacturing, marketing, selling, offering to sell and/or importing Albuterol ANDA Product soon after FDA approval.

116. Such conduct will constitute direct infringement of one or more claims of the ’289 patent under 35 U.S.C. § 271(a), inducement of infringement of the ’289 patent under 35 U.S.C.§ 271(b), and contributory infringement of the ’289 patent under 35 U.S.C. § 271(c).

117. Lupin’s infringing patent activity complained of herein is imminent and will begin following FDA approval of the ANDA.

118. 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 '289 patent. Lupin's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

119. Upon information and belief, Lupin will knowingly and willfully infringe the '289 patent.

120. Teva will be irreparably harmed if Lupin is not enjoined from infringing the '289 patent.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

(a) declaring that the '152 patent is valid and enforceable;

(b) declaring that Defendants have infringed one or more claims of the '152 patent by the filing of ANDA No. 209954 with a paragraph (IV) certification, 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 Lupin's generic Albuterol ANDA Product prior to the expiration of the '152 patent and any regulatory exclusivities;

(c) declaring that the '712 patent is valid and enforceable;

(d) declaring that Defendants have infringed one or more claims of the '712 patent by the filing of ANDA No. 209954 with a paragraph (IV) certification, and would infringe one or more claims of the '712 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Lupin's generic Albuterol ANDA Product prior to the expiration of the '712 patent and any regulatory exclusivities;

(e) declaring that the ’289 patent is valid and enforceable;

(f) declaring that Defendants have infringed one or more claims of the ’289 patent by the filing of ANDA No. 209954 with a paragraph (IV) certification, and would infringe one or more claims of the ’289 patent by the threatened acts of importation, manufacture, use, offering to sell and sale of Lupin’s generic Albuterol ANDA Product prior to the expiration of the ’289 patent and any regulatory exclusivities;

(g) ordering that the effective date of the FDA approval of Lupin’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);

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

(i) 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 Lupin’s generic Albuterol ANDA Product prior to the expiration of the patents-in-suit;

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

(k) in the event that Lupin obtains final approval for Lupin’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 Lupin'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

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

*/s/ Nathan R. Hoeschen*

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
300 Delaware Avenue, Suite 1120
SHAW KELLER LLP
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com
*Attorneys for Plaintiffs*

OF COUNSEL:
Daryl L. Wiesen
Nicholas K. Mitrokostas
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000

Andrew E. Riley
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
(212) 813-8800

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