

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TEVA BRANDED PHARMACEUTICAL	:	Civil Action No. 21-13240-FLW-RLS
PRODUCTS R&D, INC., and	:	
AUSPEX PHARMACEUTICALS, INC.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
AUROBINDO PHARMA LTD., and	:	
AUROBINDO PHARMA USA, INC.	:	
	:	
Defendants.	:	
	:	

FIRST AMENDED COMPLAINT

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. (“Teva”) and Auspex Pharmaceuticals, Inc. (“Auspex”) (collectively, “Plaintiffs”), by their attorneys, for their First Amended Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Aurobindo Pharma Ltd. of Abbreviated New Drug Application (“ANDA”) No. 215971 (“Aurobindo’s ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions (“Aurobindo’s ANDA Products”) of Plaintiffs’ AUSTEDO® (deutetrabenazine) products prior to the expiration of U.S. Patent Nos. 8,524,733 (the “’733 patent”), 9,233,959 (the “’959 patent”), 9,296,739 (the “’739 patent”), 9,550,780 (the “’780 patent”); 9,814,708 (the “’708 patent”), 10,959,996 (the “’996 patent”), and 11,179,386 (the “’386 patent”). Collectively, the ’733 patent, the ’959 patent, the ’739 patent, the ’780 patent, the ’708 patent, the ’996 patent, and the ’386 patent are referred to herein as the “Patents-in-Suit.”

PARTIES

2. Plaintiff Teva is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

3. Teva is the holder of New Drug Application (“NDA”) No. 208082 for AUSTEDO® 6 mg, 9 mg, and 12 mg (deutetrabenazine) Tablet, Oral. Teva’s AUSTEDO® tablets are approved by the FDA for treatment of both tardive dyskinesia in adults and chorea associated with Huntington’s disease.

4. Plaintiff Auspex is a company organized under the laws of the State of Delaware with its principal place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

5. Upon information and belief, defendant Aurobindo Pharma, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad 500038, Telangana, India. Upon information and belief, Aurobindo Pharma, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Aurobindo Pharma USA, Inc.

6. Upon information and belief, defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

7. On information and belief, Aurobindo Pharma USA, Inc. operates a distribution center at 6 Wheeling Road, Dayton, New Jersey 08810.

8. On information and belief, Aurobindo Pharma, Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the state of New Jersey, through its own actions and through the actions of its agents and subsidiaries from which Aurobindo Ltd. derives a substantial portion of its revenue.

9. Upon information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma, Ltd.

10. Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. are collectively referred to herein as “Aurobindo.”

11. Upon information and belief, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit Aurobindo’s ANDA to the FDA.

12. Upon information and belief, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. know and intend that upon approval of Aurobindo’s ANDA, Aurobindo Pharma, Ltd. will manufacture Aurobindo’s ANDA Products and Aurobindo Pharma USA, Inc. will directly or indirectly market, sell, and distribute Aurobindo’s ANDA Products throughout the United States, including in New Jersey.

13. On information and belief, following any FDA approval of Aurobindo’s ANDA, Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. will act in concert to distribute and sell Aurobindo’s ANDA Products throughout the United States, including within New Jersey.

JURISDICTION

14. Plaintiffs incorporate each of the preceding paragraphs 1–13 as if fully set forth herein.

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

16. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Aurobindo.

17. Aurobindo Pharma, Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Aurobindo Pharma, Ltd., itself and through its wholly owned subsidiary Aurobindo Pharma USA, Inc., has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Aurobindo Pharma, Ltd., itself and through its wholly owned subsidiary Aurobindo Pharma USA, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Aurobindo Pharma, Ltd. is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Aurobindo Pharma USA, Inc., and therefore the activities of Aurobindo Pharma USA, Inc. in this jurisdiction are attributed to Aurobindo Pharma, Ltd.

18. Aurobindo Pharma USA, Inc. is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. For example, Aurobindo Pharma USA, Inc.'s principal place of business is located in New Jersey. In addition, on information and belief, Aurobindo Pharma USA, Inc. develops, manufactures,

imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

19. In addition, this Court has personal jurisdiction over Aurobindo because, among other things, on information and belief: (1) Aurobindo filed Aurobindo's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products in the United States, including in New Jersey; and (2) upon approval of Aurobindo's ANDA, Aurobindo will market, distribute, offer for sale, sell, and/or import Aurobindo's ANDA Products in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Aurobindo's ANDA Products in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Aurobindo's ANDA, Aurobindo's ANDA Products will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

20. In addition, this Court has personal jurisdiction over Aurobindo because Aurobindo Pharma, Ltd. and Aurobindo Pharma USA, Inc. regularly (1) engage in patent litigation concerning Aurobindo's ANDA products in this District, (2) do not contest personal jurisdiction in this District, and (3) purposefully avail themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g., Chiesi USA, Inc. et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 3:19-cv-18756-FLW-LHG (D.N.J. Oct. 7,

2019); *Actelion Pharm. Ltd. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 3:19-cv-15437-FLW-LHG (D.N.J. July 16, 2019); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 2:19-cv-05799-ES-MAH (D.N.J. Feb. 14, 2019).

21. For the above reasons, it would not be unfair or unreasonable for Aurobindo to litigate this action in this District, and the Court has personal jurisdiction over it here.

VENUE

22. Plaintiffs incorporate each of the proceeding paragraphs 1–21 as if fully set forth herein.

23. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Aurobindo Pharma, Ltd., at least because, on information and belief, Aurobindo Pharma, Ltd. is a foreign corporation that may be sued in any judicial district in which it is subject to the Court’s personal jurisdiction.

24. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) as to Aurobindo Pharma USA, Inc. because, on information and belief, Aurobindo Pharma USA, Inc. has a regular and established place of business in New Jersey, and because, on information and belief, Aurobindo Pharma USA, Inc. has committed or aided, abetted, contributed to, and/or participated in the commission of acts of infringement of the Patents-in-Suit that will lead to foreseeable harm and injury to Plaintiffs by preparing or assisting in preparing Aurobindo’s ANDA in New Jersey and/or with the intention of seeking to market the Aurobindo ANDA Products nationwide, including within New Jersey.

25. Moreover, Aurobindo has not contested venue in New Jersey in one or more prior cases arising out of the filing of its ANDAs. See, e.g., *Chiesi USA, Inc. et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 3:19-cv-18756-FLW-LHG (D.N.J. Oct. 7, 2019);

Actelion Pharm. Ltd. v. Aurobindo Pharma USA, Inc. et al., Civil Action No. 3:19-cv-15437-FLW-LHG (D.N.J. July 16, 2019); *Celgene Corp. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 2:19-cv-05799-ES-MAH (D.N.J. Feb. 14, 2019).

BACKGROUND

The '733 Patent

26. The '733 patent, entitled “Benzoquinoline Inhibitors of Vesicular Monoamine Transporter 2” (Exhibit A), duly and legally issued on September 3, 2013.

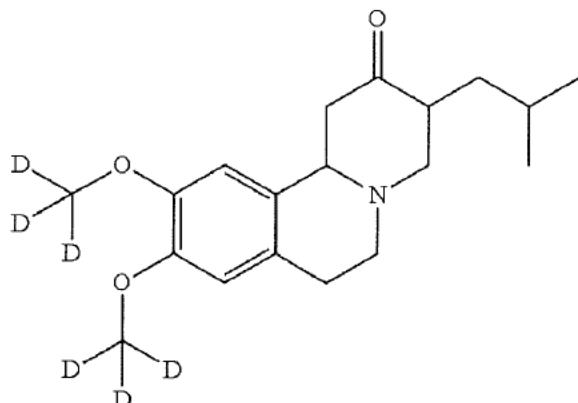
27. Auspex is the owner and assignee of the '733 patent.

28. The '733 patent lists as inventors Thomas G. Gant and Manoucherhr M. Shahbaz.

29. The '733 patent is listed in connection with AUSTEDO® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the “Orange Book.”

30. Claim 1 of the '733 patent claims:

1. A compound having the structural formula:



or a salt thereof, wherein each position represented as D has deuterium enrichment of no less than about 90%.

The '959 Patent

31. The '959 patent, entitled "Formulations and Pharmacokinetics of Deuterated Benzoquinoline Inhibitors of Vesicular Monoamine Transporter 2" (Exhibit B), duly and legally issued on January 12, 2016.

32. Auspex is the owner and assignee of the '959 patent.

33. The '959 patent lists as inventors Andreas Sommer, Chengzhi Zhang, John Carter, John Arthur, Margaret Bradbury, Thomas Gant, and Manouchehr Shahbaz.

34. The '959 patent is listed in connection with AUSTEDO® in the Orange Book.

35. Claim 1 of the '959 patent claims:

1. A pharmaceutical composition comprising, in a solid dosage form for oral delivery of between about 100 mg and about 1 g total weight:

between about 2% and about 18% of d₆-tetrabenazine;
between about 60% and about 70% mannitol;
between about 15% and about 25% microcrystalline cellulose;
between about 1% and about 10% of a polyvinylpyrrolidone;
between about 0.5% and about 2% of a polysorbate;
between about 5% and about 20% of a poly(ethylene oxide) polymer; and
between about 0.5% and about 2% of magnesium stearate.

The '739 Patent

36. The '739 patent, entitled "Formulations and Pharmacokinetics of Deuterated Benzoquinoline Inhibitors of Vesicular Monoamine Transporter 2" (Exhibit C), duly and legally issued on March 29, 2016.

37. Auspex is the owner and assignee of the '739 patent.

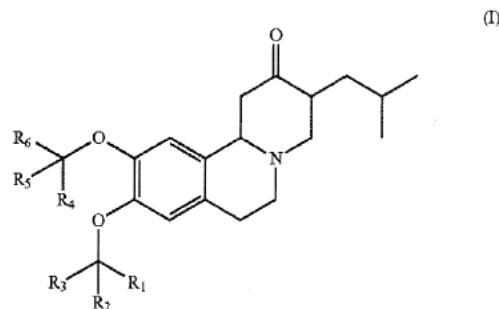
38. The '739 patent lists as inventors Andreas Sommer, Chengzhi Zhang, John Carter, John Arthur, Margaret Bradbury, Thomas Gant, and Manouchehr Shahbaz.

39. The '739 patent is listed in connection with AUSTEDO® in the Orange Book.

40. Claim 1 of the '739 patent claims:

1. A pharmaceutical composition comprising, in a solid dosage form for oral delivery of between about 100 mg and about 1 g total weight:

between about 2% and about 18% of a mixture of compounds of structural Formula I



or a salt thereof, wherein:

R₁-R₆ are independently selected from the group consisting of hydrogen and deuterium, and the composition has deuterium enrichment of at least 10% in the compounds of Formula I;

between about 60% and about 70% mannitol;
between about 15% and about 25% microcrystalline cellulose;
between about 1% and about 10% of a polyvinylpyrrolidone;
between about 0.5% and about 2% of a polysorbate;
between about 5% and about 20% of a poly(ethylene oxide) polymer;
and
between about 0.5% and about 2% of magnesium stearate.

The '780 Patent

41. The '780 patent, entitled "Formulations Pharmacokinetics of Deuterated Benzoquinoline Inhibitors of Vesicular Monoamine Transporter 2" (Exhibit D), duly and legally issued on January 24, 2017.

42. Auspex is the owner and assignee of the '780 patent.

43. The '780 patent lists as inventors Andreas Sommer, Chengzhi Zhang, John Carter, John Arthur, Margaret Bradbury, Thomas Gant, and Manouchehr Shahbaz.

44. The '780 patent is listed in connection with AUSTEDO® in the Orange Book.

45. Claim 1 of the '780 Patent claims:

1. A compound that is crystalline d₆-tetrabenazine Form I having deuterium enrichment of no less than about 1%, and having an X-ray diffractogram comprising peaks, in terms of 2θ±0.2, at 6.5, 12.2, 14.4, 22.4 and 23.4; or a pharmaceutically acceptable salt or hydrate thereof.

The '708 Patent

46. The '708 patent, entitled "Formulations and Pharmacokinetics of Deuterated Benzoquinoline Inhibitors of Vesicular Monoamine Transporter 2" (Exhibit E), duly and legally issued on November 14, 2017.

47. Auspex is the owner and assignee of the '708 patent.

48. The '708 patent lists as inventors Andreas Sommer, Chengzhi Zhang, John Carter, John Arthur, Margaret Bradbury, Thomas Gant, and Manouchehr Shahbaz.

49. The '708 patent is listed in connection with AUSTEDO® in the Orange Book.

50. Claim 1 of the '708 patent claims:

1. An extended-release pharmaceutical formulation

comprising 6 to 24 mg of d₆-tetrabenazine and between about 5% and about 20% by weight, based on the weight of the formulation, of a poly(ethylene oxide) polymer, wherein upon administration to a subject:

the formulation provides a reduction in dose relative to a formulation comprising non-deuterated tetrabenazine; and maintains at least the same AUC of the total combined amount of d₆-α-dihydrotetrabenazine and d₆-β-dihydrotetrabenazine relative to α-dihydrotetrabenazine and β-dihydrotetrabenazine of the formulation comprising non-deuterated tetrabenazine.

The '996 Patent

51. The '996 patent, entitled "Methods for the Treatment of Abnormal Involuntary Movement Disorders" (Exhibit F), duly and legally issued on March 30, 2021.

52. Auspex is the owner and assignee of the '996 patent.

53. The '996 patent lists as inventors David Stamler and Michael Fangching Huang.

54. The '996 patent is listed in connection with AUSTEDO® in the Orange Book.

55. Claim 1 of the '996 patent claims:

1. A method of transitioning a human from tetrabenazine to deutetabenazine for the treatment of chorea associated with Huntington's disease, comprising:

a) discontinuing a daily amount of tetrabenazine; and
b) administering an initial daily amount of deutetabenazine the next day to the human,

wherein the daily amount of tetrabenazine is 12.5 mg and the initial total daily amount of deutetabenazine is 6 mg; or wherein the daily amount of tetrabenazine is 25 mg and the initial total daily amount of deutetabenazine is 12 mg; or wherein the daily amount of tetrabenazine is 37.5 mg and the initial total daily amount of deutetabenazine is 18 mg; or

wherein the daily amount of tetrabenazine is 50 mg and the initial total daily amount of deutetabenazine is 24 mg; or wherein the daily amount of tetrabenazine is 62.5 mg and the initial total daily amount of deutetabenazine is 30 mg; or

wherein the daily amount of tetrabenazine is 75 mg and the initial total daily amount of deutetabenazine is 36 mg; or wherein the daily amount of tetrabenazine is 87.5 mg and the initial total daily amount of deutetabenazine is 42 mg; or

wherein the daily amount of tetrabenazine is 100 mg and the initial total daily amount of deutetabenazine is 48 mg.

The '386 Patent

56. The '386 patent, entitled "Analogs of Deutetabenazine, Their Preparation and Use" (Exhibit G), duly and legally issued on November 23, 2021.

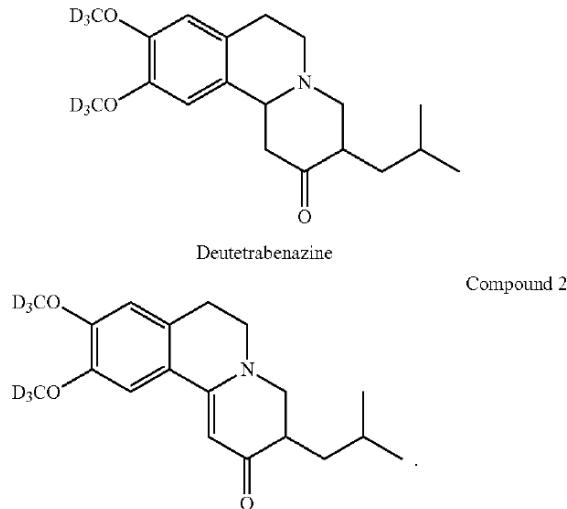
57. Auspex is the owner and assignee of the '386 patent.

58. The '386 patent lists as inventors Chengzhi Zhang and James Kerr.

59. The '386 patent is listed in connection with AUSTEDO® in the Orange Book.

60. Claim 1 of the '386 patent claims:

A pharmaceutical composition in the form of a tablet comprising an admixture of a deutetabenazine drug substance and a pharmaceutically acceptable carrier, wherein the deutetabenazine drug substance comprises 5 mg to 30 mg of deutetabenazine; and Compound 2 in an amount that is not more than 0.15 area %, relative to the concentration of the deutetabenazine in the tablet, based on a determination by an HPLC method comprising a C18, 150x4.6 mm, 3.5 µm column and a photodiode array/ultraviolet detector at 220 nm



INFRINGEMENT BY AUROBINDO

61. By letters dated May 20, 2021 (“Aurobindo’s First Notice Letter”) and April 14, 2022 (“Aurobindo’s Second Notice Letter”) (collectively, “Aurobindo’s Notice Letters”), Aurobindo notified Plaintiffs that it had filed a Paragraph IV Certification with respect to the Patents-in-Suit and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Products prior to the expiration of the Patents-in-Suit. On information and belief, Aurobindo’s ANDA contains a Paragraph IV Certification asserting that the Patents-in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Aurobindo’s ANDA Products, and/or that the Patents-in-Suit are invalid and/or unenforceable.

62. The purpose of Aurobindo’s submission of Aurobindo’s ANDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Products prior to the expiration of the Patents-in-Suit.

63. In Aurobindo's Notice Letters, Aurobindo stated that the subject of Aurobindo's ANDA is deutetabenazine tablets, 6 mg, 9 mg, and 12 mg.

64. In Aurobindo's Notice Letters, Aurobindo stated that the active ingredient of Aurobindo's ANDA Products is deutetabenazine.

65. In Aurobindo's Notice Letters, Aurobindo stated that the proposed dosage strengths of Aurobindo's ANDA Products are 6 mg, 9 mg, and 12 mg of deutetabenazine.

66. In Aurobindo's Notice Letters, Aurobindo stated that the dosage form of Aurobindo's ANDA Products is an oral tablet.

67. In an exchange of correspondence following Aurobindo's First Notice Letter, counsel for Plaintiffs and counsel for Aurobindo discussed the terms of Aurobindo's Offer of Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, Aurobindo's ANDA and the Drug Master File referred to therein.

68. This action was commenced before the expiration of forty-five days from the date of the receipt of Aurobindo's First Notice Letter.

**COUNT I – INFRINGEMENT BY AUROBINDO
OF THE '733 PATENT UNDER 35 U.S.C. § 271(e)(2)**

69. Plaintiffs incorporate each of the preceding paragraphs 1–68 as if fully set forth herein.

70. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '733 patent was an act of infringement of the '733 patent under 35 U.S.C. § 271(e)(2)(A).

71. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '733 patent, recited above, either literally or under the doctrine of equivalents.

72. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

73. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '733 patent, recited above.

74. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '733 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

75. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '733 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '733 patent after approval of Aurobindo's ANDA.

76. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '733 patent, active inducement of infringement of the '733 patent, and contribution to the infringement by others of the '733 patent.

77. On information and belief, Aurobindo has acted with full knowledge of the '733 patent and without a reasonable basis for believing that it would not be liable for infringing

the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement by others of the '733 patent.

78. Unless Aurobindo is enjoined from infringing the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement by others of the '733 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT II – INFRINGEMENT BY AUROBINDO
OF THE '959 PATENT UNDER 35 U.S.C. § 271(e)(2)**

79. Plaintiffs incorporate each of the preceding paragraphs 1–78 as if fully set forth herein.

80. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '959 patent was an act of infringement of the '959 patent under 35 U.S.C. § 271(e)(2)(A).

81. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '959 patent, recited above, either literally or under the doctrine of equivalents.

82. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

83. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '959 patent, recited above.

84. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '959 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

85. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '959 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '959 patent after approval of Aurobindo's ANDA.

86. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '959 patent, active inducement of infringement of the '959 patent, and contribution to the infringement by others of the '959 patent.

87. On information and belief, Aurobindo has acted with full knowledge of the '959 patent and without a reasonable basis for believing that it would not be liable for infringing the '959 patent, actively inducing infringement of the '959 patent, and contributing to the infringement by others of the '959 patent.

88. Unless Aurobindo is enjoined from infringing the '959 patent, actively inducing infringement of the '959 patent, and contributing to the infringement by others of the '959 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT III – INFRINGEMENT BY AUROBINDO
OF THE '739 PATENT UNDER 35 U.S.C. § 271(e)(2)**

89. Plaintiffs incorporate each of the preceding paragraphs 1–88 as if fully set forth herein.

90. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '739 patent was an act of infringement of the '739 patent under 35 U.S.C. § 271(e)(2)(A).

91. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '739 patent, recited above, either literally or under the doctrine of equivalents.

92. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

93. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '739 patent, recited above.

94. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '739 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

95. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '739 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '739 patent after approval of Aurobindo's ANDA.

96. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '739 patent, active inducement of infringement of the '739 patent, and contribution to the infringement by others of the '739 patent.

97. On information and belief, Aurobindo has acted with full knowledge of the '739 patent and without a reasonable basis for believing that it would not be liable for infringing the '739 patent, actively inducing infringement of the '739 patent, and contributing to the infringement by others of the '739 patent.

98. Unless Aurobindo is enjoined from infringing the '739 patent, actively inducing infringement of the '739 patent, and contributing to the infringement by others of the '739 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IV – INFRINGEMENT BY AUROBINDO
OF THE '780 PATENT UNDER 35 U.S.C. § 271(e)(2)**

99. Plaintiffs incorporate each of the preceding paragraphs 1–98 as if fully set forth herein.

100. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '780 patent was an act of infringement of the '780 patent under 35 U.S.C. § 271(e)(2)(A).

101. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '780 patent, recited above, either literally or under the doctrine of equivalents.

102. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

103. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '780 patent, recited above.

104. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '780 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

105. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '780 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '780 patent after approval of Aurobindo's ANDA.

106. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '780 patent, active inducement of infringement of the '780 patent, and contribution to the infringement by others of the '780 patent.

107. On information and belief, Aurobindo has acted with full knowledge of the '780 patent and without a reasonable basis for believing that it would not be liable for infringing the '780 patent, actively inducing infringement of the '780 patent, and contributing to the infringement by others of the '780 patent.

108. Unless Aurobindo is enjoined from infringing the '780 patent, actively inducing infringement of the '780 patent, and contributing to the infringement by others of the '780 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT V – INFRINGEMENT BY AUROBINDO
OF THE '708 PATENT UNDER 35 U.S.C. § 271(e)(2)**

109. Plaintiffs incorporate each of the preceding paragraphs 1–108 as if fully set forth herein.

110. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

111. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '708 patent, recited above, either literally or under the doctrine of equivalents.

112. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

113. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '708 patent, recited above.

114. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '708 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

115. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '708 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '708 patent after approval of Aurobindo's ANDA.

116. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '708 patent, active inducement of infringement of the '708 patent, and contribution to the infringement by others of the '708 patent.

117. On information and belief, Aurobindo has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent.

118. Unless Aurobindo is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VI – INFRINGEMENT BY AUROBINDO
OF THE '996 PATENT UNDER 35 U.S.C. § 271(e)(2)**

119. Plaintiffs incorporate each of the preceding paragraphs 1–118 as if fully set forth herein.

120. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '996 patent was an act of infringement of the '996 patent under 35 U.S.C. § 271(e)(2)(A).

121. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '996 patent, recited above, either literally or under the doctrine of equivalents.

122. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

123. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '996 patent, recited above.

124. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '996 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

125. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '996 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '996 patent after approval of Aurobindo's ANDA.

126. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '996 patent, active inducement of infringement of the '996 patent, and contribution to the infringement by others of the '996 patent.

127. On information and belief, Aurobindo has acted with full knowledge of the '996 patent and without a reasonable basis for believing that it would not be liable for infringing

the '996 patent, actively inducing infringement of the '996 patent, and contributing to the infringement by others of the '996 patent.

128. Unless Aurobindo is enjoined from infringing the '996 patent, actively inducing infringement of the '996 patent, and contributing to the infringement by others of the '996 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VII – INFRINGEMENT BY AUROBINDO
OF THE '386 PATENT UNDER 35 U.S.C. § 271(e)(2)**

129. Plaintiffs incorporate each of the preceding paragraphs 1–128 as if fully set forth herein.

130. Aurobindo's submission of Aurobindo's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products prior to the expiration of the '386 patent was an act of infringement of the '386 patent under 35 U.S.C. § 271(e)(2)(A).

131. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '386 patent, recited above, either literally or under the doctrine of equivalents.

132. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products immediately and imminently upon FDA approval of Aurobindo's ANDA.

133. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '386 patent, recited above.

134. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '386 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

135. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '386 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '386 patent after approval of Aurobindo's ANDA.

136. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '386 patent, active inducement of infringement of the '386 patent, and contribution to the infringement by others of the '386 patent.

137. On information and belief, Aurobindo has acted with full knowledge of the '386 patent and without a reasonable basis for believing that it would not be liable for infringing the '386 patent, actively inducing infringement of the '386 patent, and contributing to the infringement by others of the '386 patent.

138. Unless Aurobindo is enjoined from infringing the '386 patent, actively inducing infringement of the '386 patent, and contributing to the infringement by others of the '386 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '733 PATENT**

139. Plaintiffs incorporate each of the preceding paragraphs 1–138 as if fully set forth herein.

140. Aurobindo has knowledge of the '733 patent.

141. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '733 patent, recited above, either literally or under the doctrine of equivalents.

142. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

143. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '733 patent, recited above.

144. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '733 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

145. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '733 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '733 patent after approval of Aurobindo's ANDA.

146. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '733 patent, active inducement of infringement of the '733 patent, and contribution to the infringement by others of the '733 patent.

147. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement by others of the '733 patent.

148. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether the claims of the '733 patent are valid.

149. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '733 patent and that the claims of the '733 patent are valid.

150. Aurobindo should be enjoined from infringing the '733 patent, actively inducing infringement of the '733 patent, and contributing to the infringement by others of the '733 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT IX – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '959 PATENT**

151. Plaintiffs incorporate each of the preceding paragraphs 1–150 as if fully set forth herein.

152. Aurobindo has knowledge of the '959 patent.

153. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '959 patent, recited above, either literally or under the doctrine of equivalents.

154. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

155. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '959 patent, recited above.

156. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '959 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

157. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '959 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '959 patent after approval of Aurobindo's ANDA.

158. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '959 patent, active inducement of infringement of the '959 patent, and contribution to the infringement by others of the '959 patent.

159. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '959 patent, actively inducing infringement of the '959 patent, and contributing to the infringement by others of the '959 patent.

160. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed labeling according to Aurobindo's ANDA will infringe at least claim 1 of the '959 patent, recited above.

161. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '959 patent and that the claims of the '959 patent are valid.

162. Aurobindo should be enjoined from infringing the '959 patent, actively inducing infringement of the '959 patent, and contributing to the infringement by others of the '959 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '739 PATENT**

163. Plaintiffs incorporate each of the preceding paragraphs 1–162 as if fully set forth herein.

164. Aurobindo has knowledge of the '739 patent.

165. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '739 patent, recited above, either literally or under the doctrine of equivalents.

166. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

167. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '739 patent, recited above.

168. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '739 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

169. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '739 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '739 patent after approval of Aurobindo's ANDA.

170. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '739 patent, active inducement of infringement of the '739 patent, and contribution to the infringement by others of the '739 patent.

171. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '739 patent, actively inducing infringement of the '739 patent, and contributing to the infringement by others of the '739 patent.

172. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed labeling according to Aurobindo's ANDA will infringe at least claim 1 of the '739 patent, recited above.

173. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '739 patent and that the claims of the '739 patent are valid.

174. Aurobindo should be enjoined from infringing the '739 patent, actively inducing infringement of the '739 patent, and contributing to the infringement by others of the '739 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XI – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '780 PATENT**

175. Plaintiffs incorporate each of the preceding paragraphs 1–174 as if fully set forth herein.

176. Aurobindo has knowledge of the '780 patent.

177. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '780 patent, recited above, either literally or under the doctrine of equivalents.

178. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

179. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '780 patent, recited above.

180. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '780 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

181. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '780 patent and

that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '780 patent after approval of Aurobindo's ANDA.

182. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '780 patent, active inducement of infringement of the '780 patent, and contribution to the infringement by others of the '780 patent.

183. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '780 patent, actively inducing infringement of the '780 patent, and contributing to the infringement by others of the '780 patent.

184. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether the claims of the '780 patent are valid.

185. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '780 patent and that the claims of the '780 patent are valid.

186. Aurobindo should be enjoined from infringing the '780 patent, actively inducing infringement of the '780 patent, and contributing to the infringement by others of the '780 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '708 PATENT**

187. Plaintiffs incorporate each of the preceding paragraphs 1–186 as if fully set forth herein.

188. Aurobindo has knowledge of the '708 patent.

189. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '708 patent, recited above, either literally or under the doctrine of equivalents.

190. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

191. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '708 patent, recited above.

192. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '708 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

193. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '708 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '708 patent after approval of Aurobindo's ANDA.

194. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '708 patent, active inducement of infringement of the '708 patent, and contribution to the infringement by others of the '708 patent.

195. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent.

196. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether Aurobindo's manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's ANDA Products with their proposed labeling according to Aurobindo's ANDA will infringe at least claim 1 of the '708 patent, recited above.

197. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '708 patent and that the claims of the '708 patent are valid.

198. Aurobindo should be enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIII – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '996 PATENT**

199. Plaintiffs incorporate each of the preceding paragraphs 1–198 as if fully set forth herein.

200. Aurobindo has knowledge of the '996 patent.

201. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '996 patent, recited above, either literally or under the doctrine of equivalents.

202. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

203. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '996 patent, recited above.

204. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '996 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

205. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '996 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '996 patent after approval of Aurobindo's ANDA.

206. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '996 patent, active inducement of infringement of the '996 patent, and contribution to the infringement by others of the '996 patent.

207. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '996 patent, actively inducing infringement of the '996 patent, and contributing to the infringement by others of the '996 patent.

208. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether the claims of the '996 patent are valid.

209. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '996 patent and that the claims of the '996 patent are valid.

210. Aurobindo should be enjoined from infringing the '996 patent, actively inducing infringement of the '996 patent, and contributing to the infringement by others of the '996 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT XIV – DECLARATORY JUDGMENT OF INFRINGEMENT
BY AUROBINDO OF THE '386 PATENT**

211. Plaintiffs incorporate each of the preceding paragraphs 1–210 as if fully set forth herein.

212. Aurobindo has knowledge of the '386 patent.

213. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products would infringe at least claim 1 of the '386 patent, recited above, either literally or under the doctrine of equivalents.

214. On information and belief, Aurobindo will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling upon FDA approval of Aurobindo's ANDA.

215. On information and belief, the use of Aurobindo's ANDA Products in accordance with and as directed by Aurobindo's proposed labeling for those products would infringe at least claim 1 of the '386 patent, recited above.

216. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '386 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so after approval.

217. On information and belief, Aurobindo knows that its ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '386 patent and that its ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '386 patent after approval of Aurobindo's ANDA.

218. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '386 patent, active inducement of infringement of the '386 patent, and contribution to the infringement by others of the '386 patent.

219. On information and belief, Aurobindo has acted without a reasonable basis for believing that it would not be liable for infringing the '386 patent, actively inducing infringement of the '386 patent, and contributing to the infringement by others of the '386 patent.

220. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Aurobindo regarding whether the claims of the '386 patent are valid.

221. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Aurobindo's ANDA Products with their proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '386 patent and that the claims of the '386 patent are valid.

222. Aurobindo should be enjoined from infringing the '386 patent, actively inducing infringement of the '386 patent, and contributing to the infringement by others of the '386 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

- (a) A judgment that Aurobindo has infringed, will infringe, and will induce and contribute to infringement of each of the Patents-in-Suit;
- (b) A judgment that the Patents-in-Suit are valid and enforceable;
- (c) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo's ANDA Products, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;
- (d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Aurobindo, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo's ANDA Products, or any product the making, using, offering for sale, sale, marketing, distribution, or

importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

- (e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo's ANDA Products, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;
- (f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Aurobindo engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Aurobindo's ANDA Products, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);
- (g) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;
- (h) An award of Plaintiffs' costs and expenses in this action; and

(i) Such further and other relief as this Court may deem just and proper.

Dated: May 31, 2022

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

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Local Rule 11.2 Certification

We hereby certify that, to the best of our knowledge, the matter in controversy is not the subject of any action pending in any court or of any arbitration or administrative proceeding.

Dated: May 31, 2022

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

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Local Rule 201.1 Certification

We hereby certify that the above captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

Dated: May 31, 2022

WALSH PIZZI O'REILLY FALANGA LLP

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