IN THE UNITES STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC., Plaintiffs, v. AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC, Defendants.	C.A. No. 1:16-cv-00942-SLR

DEFENDANTS AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, AND AUROLIFE PHARMA, LLC'S
AMENDED ANSWER, DEFENSES, AND SUPPLEMENTAL COUNTERCLAIMS

Defendants Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo") for their Amended Answer, Defenses, and Supplemental Counterclaims to the Complaint of Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Plaintiffs"), allege as follows:

THE PARTIES

1. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1, and therefore denies them.

2. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies them.

3. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies them.

4. Aurobindo admits that Aurobindo Pharma Ltd. is an Indian corporation with a place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad—500 038, Andhra Pradesh, India. Aurobindo further admits that Aurobindo Pharma Ltd. develops, manufactures, and applies for regulatory approval of certain pharmaceutical products. Aurobindo denies any remaining allegations in Paragraph 4.

5. Aurobindo admits that Aurobindo Pharma USA, Inc. is a Delaware corporation with a place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Aurobindo denies any remaining allegations in Paragraph 5.

6. Aurobindo admits that Aurolife Pharma LLC is a Delaware corporation with a place of business at 2400 Route 130 North, Dayton, New Jersey 08810. Aurobindo further admits that Aurolife Pharma LLC develops, manufactures, and applies for regulatory approval of certain pharmaceutical products. Aurobindo denies any remaining allegations in Paragraph 6.

7. Aurobindo admits that Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Ltd. Aurobindo further admits that Aurolife Pharma LLC is a wholly-owned subsidiary of Aurobindo Pharma USA, Inc. Aurobindo denies any remaining allegations in Paragraph 7.

8. Aurobindo admits that Aurobindo Pharma Ltd. submitted ANDA No. 209413, seeking approval from the United States Food and Drug Administration ("FDA") to engage in the commercial manufacture, use, offer for sale, sale, or importation of 50 mg mirabegron oral extended-release tablets ("Aurobindo's ANDA Product") as described therein. Aurobindo denies the remaining allegations contained in Paragraph 8.

NATURE OF ACTION

9. Paragraph 9 contains legal conclusions to which no response is required. Aurobindo admits that the Complaint purports to be a civil action alleging infringement of

United States Patent Nos. 7,342,117 ("the '117 patent"), 7,982,049 ("the '049 patent"), 8,835,474 ("the '474 patent"), and RE44,872 ("the '872 patent") (collectively, "the Patents-in-Suit"). Aurobindo further admits that Aurobindo Pharma Ltd. submitted ANDA No. 209413 with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Product. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 9 and specifically denies that this action states a proper claim for patent infringement, and further denies that Aurobindo has infringed, or will infringe, any valid claim of any of the Patents-in-Suit.

JURISDICTION AND VENUE

10. Paragraph 10 contains conclusions of law to which no response is required. Aurobindo will not contest subject matter jurisdiction for purposes of this action only. Aurobindo denies any remaining legal conclusions or allegations contained in Paragraph 10.

11. Paragraph 11 contains conclusions of law to which no response is required. Aurobindo will not contest personal jurisdiction for purposes of this action only. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 11.

12. Paragraph 12 contains conclusions of law to which no response is required. Aurobindo Pharma Ltd. will not contest personal jurisdiction for purposes of this action only. To the extent a response is required, Aurobindo admits that Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Ltd. Aurobindo further admits that Aurolife Pharma LLC is a wholly-owned subsidiary of Aurobindo Pharma USA, Inc. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 12.

13. Paragraph 13 contains conclusions of law to which no response is required. Aurobindo Pharma USA, Inc. will not contest personal jurisdiction for purposes of this action only. To the extent a response is required, Aurobindo admits that Aurobindo Pharma USA, Inc.

is a Delaware corporation. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 13.

14. Paragraph 14 contains conclusions of law to which no response is required. Aurolife Pharma LLC will not contest personal jurisdiction for purposes of this action only. To the extent a response is required, Aurobindo admits that Aurolife Pharma LLC is a Delaware corporation. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 14.

15. Paragraph 15 contains conclusions of law to which no response is required. Aurobindo will not contest personal jurisdiction for purposes of this action only. To the extent a response is required, Aurobindo denies the allegations contained in Paragraph 15.

16. Denied.

17. Aurobindo admits that Aurobindo Pharma Ltd. submitted ANDA No. 209413 under 21 U.S.C. § 355(j)(1) seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Product before the expiration of the Patents-in-Suit. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 17.

18. Aurobindo admits that Aurobindo Pharma Ltd. provided Astellas Pharma Inc. and Astellas Pharma Global Development, Inc. with a "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act" by way of a letter dated September 7, 2016 ("Aurobindo's Notice Letter"). Aurobindo further admits that Aurobindo's Notice Letter was signed by counsel for Aurobindo. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 18.

19. Denied.

20. Paragraph 20 contains conclusions of law to which no response is required. Aurobindo will not contest personal jurisdiction for purposes of this action only. To the extent a response is required, Aurobindo denies the allegations contained in Paragraph 20.

21. Paragraph 21 contains conclusions of law to which no response is required. Aurobindo will not contest venue for purposes of this action only. To the extent a response is required, Aurobindo denies the allegations contained in Paragraph 21.

FACTUAL BACKGROUND

A. The '117 Patent

22. Aurobindo admits that what purports to be a copy of the '117 patent was attached to the Complaint as Exhibit A. Aurobindo further admits that on its face and in accordance with the Certificates of Correction issued by the U.S. Patent and Trademark Office ("PTO") on December 16, 2008, and September 18, 2012, the '117 patent states that it issued on March 11, 2008. Aurobindo further admits that on its face the '117 patent is titled "α-Form or β-Form Crystal of Acetanilide Derivative." Aurobindo is without knowledge or information sufficient to form a belief as to any remaining allegations of Paragraph 22, and on that basis denies those allegations.

23. Paragraph 23 contains conclusions of law to which no response is required. To the extent a response is required, Aurobindo denies those allegations.

24. Upon information and belief, Aurobindo admits that the expiration date of the '117 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") as November 4, 2023.

B. The '049 Patent

25. Aurobindo admits that what purports to be a copy of the '049 patent was attached to the Complaint as Exhibit B. Aurobindo further admits that on its face and in accordance with

the Certificate of Correction issued by the PTO on September 16, 2014, the '049 patent states that it issued on July 19, 2011. Aurobindo further admits that on its face the '049 patent is titled "α-Form or β-Form Crystal of Acetanilide Derivative." Aurobindo is without knowledge or information sufficient to form a belief as to any remaining allegations of Paragraph 25, and on that basis denies those allegations.

26. Paragraph 26 contains conclusions of law to which no response is required. To the extent a response is required, Aurobindo denies those allegations.

27. Upon information and belief, Aurobindo admits that the expiration date of the '049 patent is listed in the Orange Book as November 4, 2023.

C. The '474 Patent

28. Aurobindo admits that what purports to be a copy of the '474 patent was attached to the Complaint as Exhibit C. Aurobindo further admits that on its face the '474 patent states that it issued on September 16, 2014, and that it is titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient." Aurobindo is without knowledge or information sufficient to form a belief as to any remaining allegations of Paragraph 28, and on that basis denies those allegations.

29. Paragraph 29 contains conclusions of law to which no response is required. To the extent a response is required, Aurobindo denies those allegations.

30. Upon information and belief, Aurobindo admits that the expiration date of the '049 patent is listed in the Orange Book as November 4, 2023.

D. The '872 Patent

31. Aurobindo admits that what purports to be a copy of the '872 patent was attached to the Complaint as Exhibit D. Aurobindo further admits that on its face the '872 patent states that it re-issued on April 29, 2014, and that it is titled "Remedy for Overactive Bladder

Comprising Acetic Acid Anilide Derivative As The Active Ingredient." Aurobindo is without knowledge or information sufficient to form a belief as to any remaining allegations of Paragraph 31, and on that basis denies those allegations.

32. Paragraph 32 contains conclusions of law to which no response is required. To the extent a response is required, Aurobindo denies those allegations.

33. Paragraph 33 contains conclusions of law to which no response is required. To the extent a response is required, Aurobindo denies those allegations.

34. Upon information and belief, Aurobindo admits that the expiration date of the '872 patent is listed in the Orange Book as November 4, 2023.

E. Myrbetriq®

35. Upon information and belief, Aurobindo admits that Astellas Pharma Global Development, Inc. is on record as the holder of New Drug Application ("NDA") No. 202611 for Myrbetriq® extended-release tablets in 25 mg and 50 mg dosage strengths, which purport to contain the active ingredient, mirabegron. Upon information and belief, Aurobindo admits that the approval date of NDA No. 202611 for both the 25 mg and 50 mg extended-release Myrbetriq® tablets is listed in the Orange Book as June 28, 2012. Upon information and belief, Aurobindo admits that U.S. Patent No. 6,346,532 ("the '532 patent") is listed in the Orange Book in connection with NDA No. 202611. Aurobindo is without knowledge or information sufficient to form a belief as to any remaining allegations of Paragraph 35, and on that basis denies those allegations.

36. Aurobindo admits that mirabegron has been referred to as (R)-2-(2-aminothiazol-4-yl)-4'- [2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 36, and on that basis denies those allegations.

37. Upon information and belief, Aurobindo admits the allegation in Paragraph 37.

38. Aurobindo admits that the face of each of the Patents-in-Suit identifies Astellas Pharma Inc. as the assignee. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 38, and on that basis denies those allegations.

39. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 39, and on that basis denies those allegations.

40. Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 40, and on that basis denies those allegations.

F. Alleged Infringement by Aurobindo

41. Aurobindo admits that pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), Aurobindo Pharma Ltd. submitted ANDA No. 209413 with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Product prior to the expiration of the Patents-in-Suit. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 41.

42. Aurobindo admits that Aurobindo Pharma Ltd. submitted ANDA No. 209413 under 21 U.S.C. § 355(j)(1) seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Product before the expiration of the Patents-in-Suit. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 42.

43. Aurobindo admits that Aurobindo's Notice Letter notified Astellas Pharma Inc. and Astellas Pharma Global Development, Inc. that ANDA No. 209413 was submitted with the FDA under 21 U.S.C. § 355(j)(1) to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Product before the expiration of

the Patents-in-Suit. Aurobindo further admits that Aurobindo's Notice Letter advised Plaintiffs that ANDA No. 209413 included, *inter alia*, certifications under 21 U.S.C. § 355(j)(2)(B)(iv), stating that that in Aurobindo's opinion, and to the best of its knowledge, the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale within the U.S., or importation into the U.S., of Aurobindo's ANDA Product. Aurobindo further states that Paragraph 43 contains allegations and/or conclusions of law to which no response is required. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 43.

44. Aurobindo admits that Aurobindo Pharma Ltd., in accordance with Section 505 (j)(2)(A)(vii)(III) of the Food, Drug and Cosmetic Act and pursuant to 21 CFR 314.94 (a)(12)(i)(A)(3), made a "Paragraph III" certification with respect to the '532 patent, stating that in Aurobindo's opinion, and to the best of its knowledge, the '532 patent will expire on March 27, 2022, and that Aurobindo Pharma Ltd. intends to market Aurobindo's ANDA Product after the expiry of the '532 patent. Aurobindo admits that the active ingredient in Aurobindo's ANDA Product is mirabegron. On information and belief, Aurobindo further admits that the active ingredient in Myrbetriq® is mirabegron. Paragraph 44 contains conclusions of law to which no response is required. Aurobindo denies any remaining allegations or conclusions of law contained in Paragraph 44.

45. Denied.

46. Paragraph 46 contains conclusions of law to which no response is required. To the extent an answer is required, Aurobindo admits that Plaintiffs filed the Complaint in the above-captioned action on October 13, 2016.

CLAIMS FOR RELIEF

COUNT I: ALLEGED DIRECT INFRINGEMENT OF THE '117 PATENT

47. Paragraph 47 contains no allegations of fact to which a response is required. To the extent a response is required, Aurobindo incorporates its responses to Paragraphs 1-46 as if fully set forth herein.

48. Denied.

49. Denied.

50. Denied.

COUNT II: ALLEGED DIRECT INFRINGEMENT OF THE '049 PATENT

51. Paragraph 51 contains no allegations of fact to which a response is required. To the extent a response is required, Aurobindo incorporates its responses to Paragraphs 1-50 as if fully set forth herein.

52. Denied.

53. Denied.

54. Denied.

COUNT III: ALLEGED DIRECT INFRINGEMENT OF THE '474 PATENT

55. Paragraph 55 contains no allegations of fact to which a response is required. To the extent a response is required, Aurobindo incorporates its responses to Paragraphs 1-54 as if fully set forth herein.

56. Denied.

57. Denied.

COUNT IV: ALLEGED INDUCEMENT TO INFRINGE THE '474 PATENT

58. Paragraph 58 contains no allegations of fact to which a response is required. To the extent a response is required, Aurobindo incorporates its responses to Paragraphs 1-57 as if fully set forth herein.

59. Aurobindo admits that Aurobindo Pharma Ltd. submitted ANDA No. 209413, containing, *inter alia*, a certification under 21 C.F.R. § 314.94(a)(12)(i)(A)(4) and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") of the Drug Price Competition and Patent Term Restoration Act of 1984 as to the '474 patent, to the FDA seeking approval to market the 50 mg mirabegron oral extended-release tablets described therein. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 59.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

COUNT V: ALLEGED CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT

67. Paragraph 67 contains no allegations of fact to which a response is required. To the extent a response is required, Aurobindo incorporates its responses to Paragraphs 1-66 as if fully set forth herein.

68. Aurobindo admits that Aurobindo Pharma Ltd. submitted ANDA No. 209413 under 21 U.S.C. § 355(j)(1) seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Product before the

expiration of the Patents-in-Suit. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 68.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

COUNT VI: ALLEGED DIRECT INFRINGEMENT OF THE '872 PATENT

73. Paragraph 73 contains no allegations of fact to which a response is required. To the extent a response is required, Aurobindo incorporates its responses to Paragraphs 1-72 as if fully set forth herein.

74. Denied.

75. Denied.

COUNT VII: ALLEGED INDUCEMENT TO INFRINGE THE '872 PATENT

76. Paragraph 76 contains no allegations of fact to which a response is required. To the extent a response is required, Aurobindo incorporates its responses to Paragraphs 1-75 as if fully set forth herein.

77. Aurobindo admits that Aurobindo Pharma Ltd. submitted ANDA No. 209413, containing, *inter alia*, a Paragraph IV certification as to the '872 patent, to the FDA seeking approval to market Aurobindo's ANDA Product. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 77.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

COUNT VIII: ALLEGED CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT

85. Paragraph 85 contains no allegations of fact to which a response is required. To the extent a response is required, Aurobindo incorporates its responses to Paragraphs 1-84 as if fully set forth herein.

86. Aurobindo admits that Aurobindo Pharma Ltd. submitted ANDA No. 209413 under 21 U.S.C. § 355(j)(1) seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, or importation of Aurobindo's ANDA Product before the expiration of the Patents-in-Suit. Aurobindo denies any remaining allegations or legal conclusions contained in Paragraph 86.

87. Denied.

88. Denied.

89. Denied.

90. Denied.

PRAYER FOR RELIEF

Aurobindo denies that Plaintiffs are entitled to any judgment or relief against Aurobindo and, therefore, specifically denies Paragraphs (A) through (I) of Plaintiffs' Prayer for Relief.

DEFENSES

First Defense (Non-Infringement of the '117 Patent)

91. The manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Product has not infringed, does not infringe, will not infringe, and

will not contribute to or induce infringement of any valid and/or enforceable claim of the '117 patent, either literally or under the doctrine of equivalents.

Second Defense (Invalidity of the '117 Patent)

92. Each claim of the '117 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112, and/or based on other judicially-created bases for invalidation.

Third Defense (Non-Infringement of the '049 Patent)

93. The manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Product has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '049 patent, either literally or under the doctrine of equivalents.

Fourth Defense (Invalidity of the '049 Patent)

94. Each claim of the '049 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112, and/or based on other judicially-created bases for invalidation.

Fifth Defense (Non-Infringement of the '474 Patent)

95. The manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Product has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '474 patent, either literally or under the doctrine of equivalents.

Sixth Defense (Invalidity of the '474 Patent)

96. Each claim of the '474 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112, and/or based on other judicially-created bases for invalidation.

Seventh Defense (Non-Infringement of the '872 Patent)

97. The manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Product has not infringed, does not infringe, will not infringe, and will not contribute to or induce infringement of any valid and/or enforceable claim of the '872 patent, either literally or under the doctrine of equivalents.

Eighth Defense (Invalidity of the '872 Patent)

98. Each claim of the '872 patent is invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112, and/or based on other judicially-created bases for invalidation.

Ninth Defense (Failure to State a Claim)

99. Plaintiffs' Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Reservation of Rights

100. Aurobindo reserves the right to assert such other defenses that may appear as discovery proceeds in this case.

DECLARATORY JUDGEMENT SUPPLEMENTAL COUNTERCLAIMS

Counterclaim Plaintiffs Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo") for their Supplemental Counterclaims against

Counterclaim Defendants Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Astellas"), allege as follows:

The Parties

1. Aurobindo Pharma Ltd. is a corporation existing under the laws of India, having a place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad—500 038, Andhra Pradesh, India.

2. Aurobindo Pharma USA, Inc. is a corporation existing under the laws of Delaware, having a place of business at 6 Wheeling Road, Dayton, New Jersey 08810.

3. Aurolife Pharma LLC is a corporation existing under the laws of Delaware, having a place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

4. On information and belief, Astellas Pharma Inc. is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

5. On information and belief, Astellas Ireland Co., Ltd. is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland.

6. On information and belief, Astellas Pharma Global Development, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062.

Jurisdiction and Venue

7. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2201, under the United States Patent Laws, 35 U.S.C. § 1 *et seq*., and under 21 U.S.C. § 355(j)(5)(C).

8. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j)(5)(C).

9. This Court has personal jurisdiction over Astellas because Astellas consented to jurisdiction by suing Aurobindo in this District.

10. This Court is the proper venue under 28 U.S.C. §§ 1391 and 21 U.S.C. § 355(j)(5)(C)(i)(II).

Background

11. This is an action for declaratory relief seeking a declaration of noninfringement and invalidity of United States Patent Nos. 7,342,117 ("the '117 patent"), 7,982,049 ("the '049 patent"), 8,835,474 ("the '474 patent"), and RE44,872 ("the '872 patent") (collectively, "the Patents-in-Suit").

12. As set forth below, Aurobindo Pharma Ltd. submitted Abbreviated New Drug Application ("ANDA") No. 209413, containing, *inter alia*, certifications under 21 C.F.R. § 314.94(a)(12)(i)(A)(4) and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") of the Drug Price Competition and Patent Term Restoration Act of 1984 as to the Patents-in-Suit, to the United States Food and Drug Administration ("FDA") seeking approval to market 50 mg mirabegron oral extended-release tablets ("Aurobindo's ANDA Product") as described therein.

13. Astellas filed a Complaint in this Court alleging that Aurobindo's act of submitting ANDA No. 209413 infringes the Patents-in-Suit and that Aurobindo's intended commercial manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product will infringe the Patents-in-Suit.

14. Aurobindo denies that it infringes any valid claim of the Patents-in-Suit.

15. Based on Astellas's filing of a Complaint against Aurobindo asserting infringement of the Patents-in-Suit, and Aurobindo's denial thereof, an actual controversy exists

between Aurobindo and Astellas as to whether Aurobindo infringes any valid claim of the Patents-in-Suit.

16. Unless enjoined, Astellas will continue to assert that Aurobindo infringes the Patents-in-Suit and will continue to impair Aurobindo's ability to market Aurobindo's ANDA Product, causing irreparable harm to Aurobindo's business.

The Patents-in-Suit and Myrbetriq®

17. The face of the '117 patent, titled "α-Form or β-Form Crystal of Acetanilide Derivative," indicates that it issued on March 11, 2008, from Application No. 10/494,018 filed on April 29, 2004.

18. On information and belief, Astellas Pharma Inc. purports to be the owner by assignment of the '117 patent.

19. On information and belief, Astellas Ireland Co., Ltd. purports to be Astellas Pharma Inc.'s exclusive licensee of the '117 patent.

20. The face of the '049 patent, titled "α-Form or β-Form Crystal of Acetanilide Derivative," indicates that it issued on July 19, 2011, from Application No. 12/007,653 filed on January 14, 2008.

21. On information and belief, Astellas Pharma Inc. purports to be the owner by assignment of the '049 patent.

22. On information and belief, Astellas Ireland Co., Ltd. purports to be Astellas Pharma Inc.'s exclusive licensee of the '049 patent.

23. The face of the '474 patent, titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient," indicates that it issued on September 16, 2014, from Application No. 13/117,638 filed on May 27, 2011.

24. On information and belief, Astellas Pharma Inc. purports to be the owner by assignment of the ’474 patent.

25. On information and belief, Astellas Ireland Co., Ltd. purports to be Astellas Pharma Inc.’s exclusive licensee of the ’474 patent.

26. The face of the ’872 patent, titled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” indicates that it re-issued on April 29, 2014, from Application No. 13/542,308 filed on July 5, 2012.

27. On information and belief, Astellas Pharma Inc. purports to be the owner by assignment of the ’872 patent.

28. On information and belief, Astellas Ireland Co., Ltd. purports to be Astellas Pharma Inc.’s exclusive licensee of the ’872 patent.

29. On information and belief, Astellas Pharma Global Development, Inc. purports to be the present holder of New Drug Application (“NDA”) No. 202611 for Myrbetriq® (mirabegron) extended-release tablets.

30. On information and belief, Astellas Pharma Global Development, Inc. purports to have contracted with Astellas Pharma US, Inc., a subsidiary of Astellas Pharma Inc., to market and sell Myrbetriq® in the United States on its behalf.

31. On information and belief, Myrbetriq® is the trademark under which Astellas markets mirabegron extended-release tablets for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

32. Under 21 U.S.C. § 355(b)(1)(G), an NDA holder must provide to the FDA the patent number and expiration date of any patent(s) that the holder believes “claims the drug for which the applicant submitted the application or which claims a method of using such drug.” The

FDA publishes these patent(s) in an electronic, publicly available database called *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book").

33. The Patents-in-Suit are listed in the Orange Book in connection with Myrbetriq®.

Aurobindo's ANDA

34. Aurobindo Pharma Ltd. submitted ANDA No. 209413 to the FDA seeking approval to market Aurobindo's ANDA Product.

35. Aurobindo's ANDA No. 209413 contains, *inter alia*, Paragraph IV certifications under 21 C.F.R. § 314.94(a)(12(i)(A)(4) and 21 U.S.C. §355(j)(2)(A)(vii)(IV) requesting FDA approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product prior to the expiration of the Patents-in-Suit.

36. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), Aurobindo provided notice of its Paragraph IV certifications to Astellas Pharma Inc. and Astellas Pharma Global Development, Inc. in a letter dated September 7, 2016 ("Aurobindo's Notice Letter").

37. On October 13, 2016, Astellas filed its Complaint, alleging infringement of the Patents-in-Suit by Aurobindo.

38. The present suit by Astellas impairs Aurobindo's ability to obtain approval of its ANDA No. 209413 and to market its 50 mg mirabegron oral extended-release tablets.

Count I
(Declaratory Judgment of Non-Infringement of the '117 Patent)

39. Aurobindo incorporates Paragraphs 1-38 of the Supplemental Counterclaims as if fully set forth herein.

40. As evidenced by Astellas's Complaint and Aurobindo's Amended Answer in this action, an actual and justiciable case or controversy exists regarding the alleged infringement of the '117 patent.

41. The manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Product will not infringe, nor contribute to or induce infringement of, any valid claim of the '117 patent, either literally or under the doctrine of equivalents, for at least the reasons set forth in Aurobindo's Notice Letter, including, by way of example and not limitation, that Aurobindo's ANDA Product does not contain a crystal of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide having heat absorption peaks at 90 to 110 °C and at 142 to 146 °C in the DSC analysis and having main peaks at around 9.68, 19.76, 20.72, 22.10 and 23.52 in the terms of 2θ(°) in the powder X-ray diffraction, as recited in claim 2 of the '117 patent. Additionally, for example, Aurobindo will not infringe claim 2 of the '117 patent under the doctrine of equivalents because expanding the scope of claim 2 of the '117 patent to encompass Aurobindo's ANDA Product would vitiate the specific crystal requirement, and would impermissibly negate at least one claim limitation or element. Furthermore, for example, each of the claims of the '117 patent that Plaintiffs could assert against Aurobindo are invalid for failing to comply with 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation, as set forth below in Count II of Aurobindo's Supplemental Counterclaims, and invalid claims cannot be infringed.

42. Aurobindo reserves the right to provide additional bases for noninfringement of the '117 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

43. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Aurobindo requests a declaration from the Court that Aurobindo does not infringe any valid claim of the '117 patent.

Count II
(Declaratory Judgment of Invalidity of the '117 Patent)

44. Aurobindo incorporates Paragraphs 1-43 of the Supplemental Counterclaims as if fully set forth herein.

45. As evidenced by Astellas's Complaint and Aurobindo's Amended Answer in this action, an actual and justiciable case or controversy exists regarding the invalidity of the '117 patent.

46. One or more claims of the '117 patent are invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation. By way of example and not limitation, one or more claims of the '117 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least over U.S. Patent No. 6,346,532, alone or in combination with other prior art and in view of the general knowledge in the art; and/or over WO 1999/020607 to Maruyama *et al*., published April 29, 1999, alone or in combination with other prior art and in view of the general knowledge in the art; and/or over International Patent Application Publication No. WO 1998/007445 to Akahane *et al*., published February 26, 1998 (also published in English as European Patent Application Publication No. EP0958835 on November 24, 1999), alone or in combination with other prior art such as one or more of the following: Gould, *Salt Selection for Basic Drugs*, 33 INT. J. PHARM., 201–217 (1986); Boatman, *et. al*., *A Four-Stage Approach to New Drug Development*, 5 PHARM. TECHNOL. 46–56 (1981); Guillory, J.K., "Ch. 5 – Generation of Polymorphs, Hydrates, Solvates,

and Amorphous Solids" in Polymorphism in Pharmaceutical Sciences (H.G. Brittain ed., Marcel Dekker New York) (1999); M.J. Jozwiakowski, Alteration of the Solid State of the Drug Substance: Polymorphs, Solvates, and Amorphous Forms, in Water-Insoluble Drug Formation 525 (Rong Liu ed., 2000); Guideline For Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances, Center for Drug Evaluation and Research, Food and Drug Administration (February 1987); Borka, L., ACTA PHARM. JUGOSL., 40:71-94 (1990); Brittain, H., J. PHARM. SCI., 86:404-412 (1997); Brittain, H., in Polymorphism in Pharmaceutical Solids, Brittain, H.G. ed., 227-278 (1999); Cardew, P.T. and Davey, R.J., PROC. R. SOC. LOND. A., 398:415-428 (1985); Fiese, E.F. and Hagen, T.A. in THE THEORY AND PRACTICE OF INDUSTRIAL PHARMACY, Lachman, L. *et al*., eds., 171-196 (1986); Guillory, J.K., "Ch. 5 – Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids" in Polymorphism in Pharmaceutical Sciences (H.G. Brittain ed., Marcel Dekker New York) (1999); Haleblian, J. and McCrone, W., J. PHARM. SCI., 58(8):911-29 (1969); Remington: The Science and Practice of Pharmacy, Gennaro, A. *et al*. eds. (29th ed. 2000); Sato, K., J. PHYS. D.: APPL. PHYS., 26:B77-B84 (1993); Bastin *et al*., *Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities*, ORG. PROCESS RES. & DEV., Vol. 4, 427-35 (July 19, 2000); Bavin, M., *Polymorphism in Process Development*, CHEMISTRY & INDUSTRY, Vol. 21, 527-29 (August 21, 1989); Byrn *et al*., *Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations*, PHARMACEUTICAL RESEARCH, Vol. 12, No. 7, 945-54, (1995); Caira, M.R., *Crystalline Polymorphism of Organic Compounds, in Design of Organic Solids*, TOPICS IN CURRENT CHEMISTRY, Vol. 198, 163-208 (1998); Gold, D.H. & Byrn, S., *Product Quality Research Initiative and Bulk Actives Post Approval Change*, DRUG INFORMATION JOURNAL, Vol. 33, 777-84 (1999); Yu *et al*., *Physical Characterization of Polymorphic Drugs: an Integrated*

Characterization Strategy, PHARMACEUTICAL SCIENCE & TECHNOLOGY TODAY, Vol. 1, No. 3, 118-27 (June 1998); *Crystallization*, 1st-4th eds, J.W.Mullin, Reed Educational and Professional Publishing (1st Edition 1961, 2nd Edition 1972, 3rd Edition 1992, or 4th Edition 2001); Allen Hunter's Youngstown State University X-Ray Structure Analysis Lab Manual: A Beginner's Introduction, Chapter XIV: Growing Single Crystals, http://lsci.epfl.ch/files/content/sites/lsci/files/load/Crystal_Growth.pdf (2000); WO2012/156998 to Peddy *et al*.; and/or in view of the general knowledge in the art.

47. Additionally and/or in the alternative, by way of example and not limitation, one or more claims of the '117 patent are invalid as obvious over claim 6 of U.S. Patent No. 6,346,532 under the doctrine of obviousness-type double patenting, in view of EP 1028111 and the general knowledge in the art.

48. Additionally and/or in the alternative, by way of example and not limitation, one or more claims of the '117 patent are invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and/or (3) failing to comply with the "definiteness" requirement. For example, the '117 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those skilled in the art can conclude that the inventors were in possession of the claimed invention as of the filing date. The '117 patent claims do not satisfy the enablement requirement at least because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The '117 patent claims do not satisfy the definiteness

requirement at least because those skilled in the art would not understand the full scope of the '117 patent claims when read in the light of the specification.

49. Aurobindo reserves the right to provide additional bases for invalidity of the '117 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

50. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Aurobindo requests a declaration from the Court that the claims of the '117 patent are invalid.

Count III
(Declaratory Judgment of Non-Infringement of the '049 Patent)

51. Aurobindo incorporates Paragraphs 1-50 of the Supplemental Counterclaims as if fully set forth herein.

52. As evidenced by Astellas's Complaint and Aurobindo's Amended Answer in this action, an actual and justiciable case or controversy exists regarding the alleged infringement of the '049 patent.

53. The manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Product will not infringe, nor contribute to or induce infringement of, any valid claim of the '049 patent, either literally or under the doctrine of equivalents, for at least the reasons set forth in Aurobindo's Notice Letter, including, by way of example and not limitation, that Aurobindo will not administer any pharmaceutical composition to patients and therefore will not directly infringe one or more claims of the '049 patent. Additionally, for example, Aurobindo's ANDA Product does not contain a β-form crystal of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide as recited in one or more claims of the '049 patent. Furthermore, for example, the use of Aurobindo's ANDA

Product for treating overactive bladder, in accordance with Aurobindo's proposed prescribing information would not literally infringe one or more claims of the '049 patent.

54. Additionally, by way of example and not limitation, Aurobindo will not induce infringement of one or more claims of the '049 patent because Aurobindo's proposed prescribing information neither indicates administering mirabegron to patients for treating diabetes, nor that Aurobindo's ANDA Product should be prescribed by physicians for treating diabetes. Furthermore, Aurobindo will not contributorily infringe one or more claims of the '049 patent because, for example, Aurobindo's ANDA Product has substantial non-infringing uses, including but not limited to, treatment of overactive bladder in patients. Additionally or in the alternative, by way of example and not limitation, each of the claims of the '117 patent that Plaintiffs could assert against Aurobindo are invalid for failing to comply with 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation, as set forth below in Count IV of Aurobindo's Supplemental Counterclaims, and invalid claims cannot be infringed.

55. Aurobindo reserves the right to provide additional bases for noninfringement of the '049 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

56. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Aurobindo requests a declaration from the Court that Aurobindo does not infringe any valid claim of the '049 patent.

Count IV
(Declaratory Judgment of Invalidity of the '049 Patent)

57. Aurobindo incorporates Paragraphs 1-56 of the Supplemental Counterclaims as if fully set forth herein.

58. As evidenced by Astellas's Complaint and Aurobindo's Amended Answer in this action, an actual and justiciable case or controversy exists regarding the invalidity of the '049 patent.

59. The claims of the '049 patent are invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation. By way of example and not limitation, one or more claims of the '049 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least over the U.S. Patent No. 6,346,532 in view of the general knowledge in the art; and/or over WO 1999/020607 to Maruyama *et al*., published April 29, 1999, in view of the general knowledge in the art; and/or over International Patent Application Publication No. WO 1998/007445 to Akahane *et al*., published February 26, 1998 (also published in English as European Patent Application Publication No. EP0958835 on November 24, 1999), alone or in combination with other prior art such as one or more of the following: Gould, *Salt Selection for Basic Drugs*, 33 INT. J. PHARM., 201–217 (1986); Boatman, *et. al*., *A Four-Stage Approach to New Drug Development*, 5 PHARM. TECHNOL. 46–56 (1981); Guillory, J.K., "Ch. 5 – Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids" in Polymorphism in Pharmaceutical Sciences (H.G. Brittain ed., Marcel Dekker New York) (1999); M.J. Jozwiakowski, Alteration of the Solid State of the Drug Substance: Polymorphs, Solvates, and Amorphous Forms, in Water-Insoluble Drug Formation 525 (Rong Liu ed., 2000); Guideline For Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances, Center for Drug Evaluation and Research, Food and Drug Administration (February 1987); Borka, L., ACTA PHARM. JUGOSL., 40:71-94 (1990); Brittain, H., J. PHARM. SCI., 86:404-412 (1997); Brittain, H., in Polymorphism in

Pharmaceutical Solids, Brittain, H.G. ed., 227-278 (1999); Cardew, P.T. and Davey, R.J., PROC. R. SOC. LOND. A., 398:415-428 (1985); Fiese, E.F. and Hagen, T.A. in THE THEORY AND PRACTICE OF INDUSTRIAL PHARMACY, Lachman, L. *et al*., eds., 171-196 (1986); Guillory, J.K., "Ch. 5 – Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids" in Polymorphism in Pharmaceutical Sciences (H.G. Brittain ed., Marcel Dekker New York) (1999); Haleblian, J. and McCrone, W., J. PHARM. SCI., 58(8):911-29 (1969); Remington: THE SCIENCE AND PRACTICE OF PHARMACY, Gennaro, A. *et al*. eds. (29th ed. 2000); Sato, K., J. PHYS. D.: APPL. PHYS., 26:B77-B84 (1993); Bastin *et al*., *Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities*, ORG. PROCESS RES. & DEV., Vol. 4, 427-35 (July 19, 2000); Bavin, M., *Polymorphism in Process Development*, CHEMISTRY & INDUSTRY, Vol. 21, 527-29 (August 21, 1989); Byrn *et al*., *Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations*, PHARMACEUTICAL RESEARCH, Vol. 12, No. 7, 945-54, (1995); Caira, M.R., *Crystalline Polymorphism of Organic Compounds, in Design of Organic Solids*, TOPICS IN CURRENT CHEMISTRY, Vol. 198, 163-208 (1998); Gold, D.H. & Byrn, S., *Product Quality Research Initiative and Bulk Actives Post Approval Change*, DRUG INFORMATION JOURNAL, Vol. 33, 777-84 (1999); Yu *et al*., *Physical Characterization of Polymorphic Drugs: an Integrated Characterization Strategy*, PHARMACEUTICAL SCIENCE & TECHNOLOGY TODAY, Vol. 1, No. 3, 118-27 (June 1998); *Crystallization*, 1st-4th eds, J.W.Mullin, Reed Educational and Professional Publishing (1st Edition 1961, 2nd Edition 1972, 3rd Edition 1992, or 4th Edition 2001); Allen Hunter's Youngstown State University X-Ray Structure Analysis Lab Manual: A Beginner's Introduction, Chapter XIV: Growing Single Crystals, http://lsci.epfl.ch/files/content/sites/lsci/files/load/Crystal_Growth.pdf (2000); WO2012/156998 to Peddy *et al*.; and/or in view of the general knowledge in the art.

60. Additionally or in the alternative, by way of example and not limitation, one or more claims of the '049 patent are invalid as obvious over claim 12 of the U.S. Patent No. 6,346,532 under the doctrine of obviousness-type double patenting, in view of EP 1028111 and the general knowledge in the art.

61. Additionally or in the alternative, by way of example and not limitation, one or more claims of the '049 patent are invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and/or (3) failing to comply with the "definiteness" requirement. The '049 patent claims do not satisfy the written description requirement because the specification fails to describe what is claimed with sufficient detail such that those skilled in the art can conclude that the inventors were in possession of the claimed invention as of the filing date. The '049 patent claims also do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the '049 patent claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the '049 patent claims when read in the light of the specification.

62. Aurobindo reserves the right to provide additional bases for invalidity of the '049 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

63. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Aurobindo requests a declaration from the Court that the claims of the '049 patent are invalid.

Count V
(Declaratory Judgment of Non-Infringement of the '474 Patent)

64. Aurobindo incorporates Paragraphs 1-63 of the Supplemental Counterclaims as if fully set forth herein.

65. As evidenced by Astellas's Complaint and Aurobindo's Amended Answer in this action, an actual and justiciable case or controversy exists regarding the alleged infringement of the '474 patent.

66. The manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Product will not infringe, nor contribute to or induce infringement of, any valid claim of the '474 patent, either literally or under the doctrine of equivalents because, by way of example and not limitation, each of the claims of the '474 patent that Plaintiffs could assert against Aurobindo are invalid for failing to comply with 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation, as set forth below in Count VI of Aurobindo's Supplemental Counterclaims, and invalid claims cannot be infringed.

67. Aurobindo reserves the right to provide additional bases for noninfringement of the '474 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

68. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Aurobindo requests a declaration from the Court that Aurobindo does not infringe any valid claim of the '474 patent.

Count VI
(Declaratory Judgment of Invalidity of the '474 Patent)

69. Aurobindo incorporates Paragraphs 1-68 of the Supplemental Counterclaims as if fully set forth herein.

70. As evidenced by Astellas's Complaint and Aurobindo's Amended Answer in this action, an actual and justiciable case or controversy exists regarding the invalidity of the '474 patent.

71. The claims of the '474 patent are invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation. By way of example and not limitation, one or more claims of the '474 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least over WO 1999/020607 to Maruyama *et al*., published April 29, 1999, and/or International Patent Application Publication No. WO 1998/007445 to Akahane *et al*., published February 26, 1998 (also published in English as European Patent Application Publication No. EP0958835 on November 24, 1999), alone or in combination with other prior art such as one or more of the following: Michel *et al*., *Effect of Diabetes on Lower Urinary Tract Symptoms in Patients With Benign Prostativ Hyperplasia*, 163 JOURNAL OF UROLOGY, 1725-1729 (2000); Yamaguchi O., *Beta3-adrenoceptors In Human Detrusor Muscle*, 59 UROLOGY (5 Suppl. 1), 25–29 (2002); WO02/00622; U.S. Patent No. 6,699,860; Canadian Patent Application Publication No. 2,305,802; Y. Igawa *et al*., *Possible* β*3-Adrenoceptor-Mediated Relaxation of the Human Detrusor*, 164 ACTA PHYSIOLOGICA 117 (1998); Yasuhiko Igawa *et al*., *Functional and Molecular Biological Evidence for a Possible* β_3*-Adrenoceptor in the Human Detrusor Muscle*, 126 BRIT. J. PHARMACOLOGY 819 (1999); Hiroo Takeda *et al*., *Effects of* β_3*-Adrenoceptor Stimulation on Prostaglandin* E_2*-Induced Bladder Hyperactivity and on the Cardiovascular System in Conscious Rats*, 21 NEUROUROLOGY & URODYNAMICS 558 (2002); Masayuki Takeda *et al*., *Evidence for* β_3*-Adrenoceptor Subtypes in Relaxation of the Human Urinary Bladder Detrusor: Analysis by Molecular Biological and*

Pharmacological Methods, 288 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 1367 (1999); Hiroo Takeda *et al*., *Role of the β_3-Adrenoceptor in Urine Storage in the Rat: Comparison Between the Selective β3-Adrenoceptor Agonist, CL316,243, and Various Smooth Muscle Relaxants*, 293 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 939 (2000); U.S. Patent No. 6,346,532; H.M. Dallosso *et al*., *The Association of Diet and Other Lifestyle Factors with Overactive Bladder and Stress Incontinence: A Longitudinal Study in Women*, 92 BJU INT'L 69 (2003); Jeanette S. Brown *et al*., *Urinary Incontinence in Older Women: Who Is at Risk?*, 87 OBSTETRICS & GYNECOLOGY 715 (1996); S. Mommsen & A. Foldspang, *Body Mass Index and Adult Female Urinary Incontinence*, 12 WORLD J. UROLOGY 319 (1994); Bosch, J.L.H.R., BJU INT'L, 83(Supp. 2):7-9 (1999); Canadian Patent Publication No. CA2398199 to Umeno *et al*.; Igawa, Y. *et al*., Proc. 1997 ICS Annual Meeting, Abstract 14, Neurourol. Urodynamics, 16:363-365; U.S. Patent No. 6,291,491 to Weber *et al*.; Woods. M. *et al*., J. UROLOGY, 166:1142-47 (2001); Blin *et al*., *Structural and Conformational Features Determining Selective Signal Transduction in the β3-Adrenergic Receptor*, MOLECULAR PHARMACOLOGY, Vol. 44, 1094-1104 (1993); Igawa *et al*., *Functional and Molecular Biological Evidence of β 3-Adrenoceptors in the Human Detrusor*, J. UROL., Vol. 157, No. 4, 175 (April 1997); Park *et al*., *Existence of β3-Adrenoceptor and its Functional Roll [sic] in the Human Ureter*, J. UROL., Vol. 157, No. 4, 77 (April 1997); Fujimura *et al*., *Expression and Possible Functional Role of the β3-Adrenoceptor in Human and Rat Detrusor Muscle*, J. UROL., Vol. 161, 680-85 (February 1999); Igawa *et al*., "Functional Investigation of Beta-Adrenoceptors in Isolated Human Detrusor – Using the Novel Selective β3-Adrenoceptor Agonist, KUC-7322," 32nd Annual Meeting of International Continence Society, Heidelberg, Germany, August 28-30, 2002; Knutson *et al*., *BPH with Coexisting Overactive Bladder Dysfunction- An Everyday Urological Dilemma*; NEUROLOGY

AND URODYNAMICS 20:237-247 (2001); Canadian Patent Application No. 02263659; Sellers *et al*., *Potential therapeutic targets for treatment of the overactive bladder*, WORLD J. UROL., 19, 307-311 (2001); Tanaka *et al*., *Discovery of Novel N-Phenylglycine Derivatives as Potent and Selective β3-Adrenoceptor Agonists for the Treatment of Frequent Urination and Urinary Incontinence*, J. MED. CHEM., 44(9):1436-1445 (2001); Yano *et al*., *The Reason Why Prostatic Hyperplasia Causes Lower Urinary Tract Symptoms*, *Asian Med. J.* 44 (2001); and/or in view of the general knowledge in the art.

72. Additionally or in the alternative, by way of example and not limitation, one or more claims of the '474 patent are invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and/or (3) failing to comply with the "definiteness" requirement. The '474 patent claims do not satisfy the written description requirement because the specification fails to describe what is claimed with sufficient detail such that those skilled in the art can conclude that the inventors were in possession of the claimed invention as of the filing date. The '474 patent claims also do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the '474 patent claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the '474 patent claims when read in the light of the specification.

73. Aurobindo reserves the right to provide additional bases for invalidity of the '474 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

74. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Aurobindo requests a declaration from the Court that the claims of the ’474 patent are invalid.

Count VII
(Declaratory Judgment of Non-Infringement of the ’872 Patent)

75. Aurobindo incorporates Paragraphs 1-74 of the Supplemental Counterclaims as if fully set forth herein.

76. As evidenced by Astellas’s Complaint and Aurobindo’s Amended Answer in this action, an actual and justiciable case or controversy exists regarding the alleged infringement of the ’872 patent.

77. The manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo’s ANDA Product will not infringe, nor contribute to or induce infringement of, any valid claim of the ’474 patent, either literally or under the doctrine of equivalents. By way of example and not limitation, Aurobindo will not directly infringe any of the claims of the ’872 patent because Aurobindo will not administer any pharmaceutical product to patients.

78. Additionally and/or in the alternative, by way of example and not limitation, the proposed prescribing information for Aurobindo’s ANDA Product does not indicate administering mirabegron to patients not suffering from diabetes, or wherein the overactive bladder is a result of benign prostatic hyperplasia, as recited in one or more claims of the ’872 patent. Nor does the proposed prescribing information for Aurobindo’s ANDA Product indicate administering mirabegron to patients not suffering from diabetes that have pollakiuria, as recited in one or more claims of the ’872 patent. Furthermore, the proposed prescribing information for Aurobindo’s ANDA Product does not indicate that Aurobindo’s ANDA Product should be prescribed by doctors for the methods purportedly claimed in the ’872 patent.

79. Additionally and/or in the alternative, by way of example and not limitation, Aurobindo will not contributorily infringe any claims of the '872 patent because Aurobindo's ANDA Product has a substantial non-infringing use, including but not limited to, treatment of overactive bladder in patients suffering from diabetes, and/or patients who do not have benign prostatic hyperplasia or pollakiuria.

80. Aurobindo reserves the right to provide additional bases for noninfringement of the '872 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

81. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Aurobindo requests a declaration from the Court that Aurobindo does not infringe any valid claim of the '872 patent.

Count VIII
(Declaratory Judgment of Invalidity of the '872 Patent)

82. Aurobindo incorporates Paragraphs 1-81 of the Supplemental Counterclaims as if fully set forth herein.

83. As evidenced by Astellas's Complaint and Aurobindo's Amended Answer in this action, an actual and justiciable case or controversy exists regarding the invalidity of the '872 patent.

84. The claims of the '872 patent are invalid for failing to comply with one or more of the conditions and requirements for patentability under Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially-created bases for invalidation. By way of example and not limitation, one or more claims of the '872 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least over WO 1999/020607 to Maruyama *et al*., published April 29, 1999, and/or International Patent Application Publication

No. WO 1998/007445 to Akahane *et al*., published February 26, 1998 (also published in English as European Patent Application Publication No. EP0958835 on November 24, 1999), alone or in combination with other prior art such as one or more of the following: Michel *et al*., *Effect of Diabetes on Lower Urinary Tract Symptoms in Patients With Benign Prostativ Hyperplasia*, 163 JOURNAL OF UROLOGY, 1725-1729 (2000); Yamaguchi O., *Beta3-adrenoceptors in Human Detrusor Muscle*, 59 UROLOGY (5 Suppl 1), 25–29 (2002); WO02/00622; U.S. Patent No. 6,699,860; Canadian Patent Application Publication No. 2,305,802; Y. Igawa *et al*., *Possible β3-Adrenoceptor-Mediated Relaxation of the Human Detrusor*, 164 ACTA PHYSIOLOGICA 117 (1998); Yasuhiko Igawa *et al*., *Functional and Molecular Biological Evidence for a Possible β_3-Adrenoceptor in the Human Detrusor Muscle*, 126 BRIT. J. PHARMACOLOGY 819 (1999); Hiroo Takeda *et al*., *Effects of β_3-Adrenoceptor Stimulation on Prostaglandin E_2-Induced Bladder Hyperactivity and on the Cardiovascular System in Conscious Rats*, 21 NEUROUROLOGY & URODYNAMICS 558 (2002); Masayuki Takeda *et al*., *Evidence for β_3-Adrenoceptor Subtypes in Relaxation of the Human Urinary Bladder Detrusor: Analysis by Molecular Biological and Pharmacological Methods*, 288 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 1367 (1999); Hiroo Takeda *et al*., *Role of the β_3-Adrenoceptor in Urine Storage in the Rat: Comparison Between the Selective β_3-Adrenoceptor Agonist, CL316,243, and Various Smooth Muscle Relaxants*, 293 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 939 (2000); U.S. Patent No. 6,346,532; H.M. Dallosso *et al*., *The Association of Diet and Other Lifestyle Factors with Overactive Bladder and Stress Incontinence: A Longitudinal Study in Women*, 92 BJU INT'L 69 (2003); Jeanette S. Brown *et al*., *Urinary Incontinence in Older Women: Who Is at Risk?*, 87 OBSTETRICS & GYNECOLOGY 715 (1996); S. Mommsen & A. Foldspang, *Body Mass Index and Adult Female Urinary Incontinence*, 12 WORLD J. UROLOGY 319 (1994); Bosch, J.L.H.R., BJU

INT'L, 83(Supp. 2):7-9 (1999); Canadian Patent Publication No. CA2398199 to Umeno *et al*.; Igawa, Y. *et al*., Proc. 1997 ICS Annual Meeting, Abstract 14, Neurourol. Urodynamics, 16:363-365; U.S. Patent No. 6,291,491 to Weber *et al*.; Woods. M. *et al*., J. Urology, 166:1142-47 (2001); Blin *et al*., *Structural and Conformational Features Determining Selective Signal Transduction in the β3-Adrenergic Receptor*, MOLECULAR PHARMACOLOGY, Vol. 44, 1094-1104 (1993); Igawa *et al*., *Functional and Molecular Biological Evidence of β 3-Adrenoceptors in the Human Detrusor*, J. UROL., Vol. 157, No. 4, 175 (April 1997); Park *et al*., *Existence of β3-Adrenoceptor and its Functional Roll [sic] in the Human Ureter*, J.UROL., Vol. 157, No. 4, 77 (April 1997); Fujimura *et al*., *Expression and Possible Functional Role of the β3-Adrenoceptor in Human and Rat Detrusor Muscle*, J. UROL. , Vol. 161, 680-85 (February 1999); Igawa *et al*., "Functional Investigation of Beta-Adrenoceptors in Isolated Human Detrusor – Using the Novel Selective β3-Adrenoceptor Agonist, KUC-7322," 32nd Annual Meeting of International Continence Society, Heidelberg, Germany, August 28-30, 2002; Knutson *et al*., *BPH with Coexisting Overactive Bladder Dysfunction- An Everyday Urological Dilemma*; NEUROLOGY AND URODYNAMICS 20:237-247 (2001); Canadian Patent Application No. 02263659; Sellers *et al*., *Potential therapeutic targets for treatment of the overactive bladder*, WORLD J. UROL., 19, 307-311 (2001); Tanaka *et al*., *Discovery of Novel N-Phenylglycine Derivatives as Potent and Selective β3-Adrenoceptor Agonists for the Treatment of Frequent Urination and Urinary Incontinence*, J. MED. CHEM., 44(9):1436-1445 (2001); Yano *et al*., *The Reason Why Prostatic Hyperplasia Causes Lower Urinary Tract Symptoms*, *Asian Med. J.* 44 (2001); Igawa *et al*., *Relaxant Effects of Isoproterenol and Selective β3-adrenoceptor Agonists on Normal, Low Compliant and Hyperreflexic Human Bladders*, J. UROL. Vol. 165, 240-244 (2001); and/or in view of the general knowledge in the art.

85. Additionally and/or in the alternative, by way of example and not limitation, one or more claims of the '872 patent are invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and/or (3) failing to comply with the "definiteness" requirement. For example, the '872 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those skilled in the art can conclude that the inventors were in possession of the claimed invention as of the filing date. The '872 patent claims do not satisfy the enablement requirement at least because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The '872 patent claims do not satisfy the definiteness requirement at least because those skilled in the art would not understand the full scope of the '872 patent claims when read in the light of the specification.

86. Aurobindo reserves the right to provide additional bases for invalidity of the '872 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

87. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., Aurobindo requests a declaration from the Court that the claims of the '872 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Aurobindo respectfully requests judgment and relief in its favor against Astellas as follows:

A. Dismissing Astellas's Complaint with prejudice and denying each and every prayer for relief contained therein;

B. Declaring that the commercial manufacture, use, sale, offer for sale, marketing, or importation of the generic 50 mg mirabegron oral extended-release tablets, as described in ANDA No. 209413, does not and will not infringe any claim of the Patents-in-Suit;

C. Declaring that the claims of the Patents-in-Suit are invalid;

D. Enjoining Astellas, its officers, employees, agents, representatives, attorneys, and others acting on its behalf, from threatening or initiating infringement litigation against Aurobindo or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Aurobindo, or charging them either orally or in writing with infringement of the Patents-in-Suit;

E. Declaring that this is an exceptional case under 35 U.S.C. § 285, and awarding Aurobindo its costs and reasonable attorneys' fees; and

F. Awarding to Aurobindo such further relief as this Court may deem necessary, just, and proper.

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