IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD. and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,	)	C.A. No. _____
Plaintiffs,	)	
v.	)	
ALKEM LABORATORIES LTD.	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc. (collectively, "Astellas" or "Plaintiffs"), by their undersigned attorneys, hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement of United States Patent Nos. 7,342,117 ("the '117 Patent"), 7,982,049 ("the '049 Patent"), 8,835,474 ("the '474 Patent") 10,842,780 ("the '780 Patent") and RE44,872 ("the '872 Patent") (collectively, the "Patents-in-suit"), arising under the United States patent laws, Title 35, United States Code. This action relates to the Abbreviated New Drug Application ("ANDA") submitted by the above-named Defendant under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration ("FDA") approval to market a generic pharmaceutical product.

THE PARTIES

A. Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc.

2. Plaintiff Astellas Pharma Inc. ("API") 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. API was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

3. Plaintiff Astellas Ireland Co., Ltd. ("AICL") 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. AICL is a subsidiary of Plaintiff API.

4. Plaintiff Astellas Pharma Global Development, Inc. ("APGD") 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. APGD is a subsidiary of Plaintiff API.

A. Alkem Laboratories Ltd. ("Alkem")

5. On information and belief, Defendant Alkem is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapti Bapat Road, Lower Parel, Mumbai, India 400 013. On information and belief, Alkem is in the business of, *inter alia*, developing, manufacturing and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

6. By a letter dated May 25, 2021, ("Alkem's Notice Letter") Alkem notified Plaintiffs that Alkem had submitted to FDA ANDA No. 215948 for mirabegron extended-release tablets, 25 mg and 50 mg ("Alkem ANDA"), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 25mg and 50mg strengths ("Alkem's ANDA Product"). On information and

belief, the purpose of Alkem's submission of the Alkem ANDA was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Alkem's ANDA Product prior to the expiration of each of the Patents-in-suit.

7. In Alkem's Notice Letter, Alkem notified Plaintiffs that, as a part of the Alkem ANDA, Alkem had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to each of the Patents-in-suit, asserting they are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Alkem's ANDA Product.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. This Court has personal jurisdiction over Alkem because, among other things, Alkem has committed tortious acts of patent infringement in filing the Alkem ANDA that has led to foreseeable harm and injury to Plaintiffs, and will imminently commit a tortious act of patent infringement by selling Alkem's ANDA Product which will lead to foreseeable harm and injury to Plaintiffs.

10. This Court also has personal jurisdiction over Alkem because its affiliations with the State of Delaware are so continuous and systematic as to render Alkem essentially at home in this forum.

11. This Court also has personal jurisdiction over Alkem pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Astellas's claims arise under federal law; (b) as a foreign defendant, Alkem is not subject to jurisdiction in any state's courts of general jurisdiction; and (c) Alkem has sufficient contacts within the United States as a whole, including but not limited to preparing and submitting an ANDA to FDA and/or manufacturing and/or selling pharmaceutical products distributed

throughout the United States, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

12. This Court also has personal jurisdiction over Alkem because it has frequently availed itself of the legal protections of the State of Delaware by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *BIAL – PORTELA & CA S.A. et al. v. Alkem Laboratories Ltd. et al.*, C.A. 21-00186-CFC (D. Del.), D.I. 6; *Otsuka Pharmaceutical Co., Ltd. et al. v. Alkem Laboratories Ltd.*, C.A. 20-01286-LPS (D. Del.), D.I. 8.

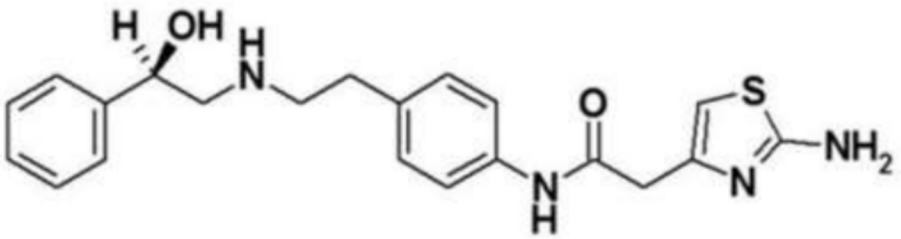
13. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Alkem.

14. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) and/or Fed. R. Civ. P. 4(k)(2).

MYRBETRIQ® TABLETS

15. APGD holds approved New Drug Application ("NDA") No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient, mirabegron. FDA approved NDA No. 202611 on June 28, 2012 for both the 25 mg and 50 mg extended-release Myrbetriq® tablets.

16. Mirabegron has been referred to chemically as, *inter alia*, (R)-2-(2-aminothiazol-4-yl)-4'-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, and 2-(2-aminothiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl]acetamide. Mirabegron can be depicted as, *inter alia*, the following formula:



17. Myrbetriq® extended-release tablets, containing 25 mg or 50 mg of mirabegron ("Myrbetriq® Tablets"), are indicated for the treatment of overactive bladder ("OAB") with symptoms of urge urinary incontinence, urgency, and urinary frequency.

18. Myrbetriq® Tablets comprise a sustained release hydrogel-forming formulation containing, *inter alia*, polyethylene oxide and polyethylene glycol as inactive ingredients within the tablet formulation, which function as a means for forming a hydrogel and a means for ensuring penetration of water into the tablets.

19. For quality control purposes in the U.S. market, Myrbetriq® Tablets are subjected to dissolution testing using the United States Pharmacopeia ("USP") Apparatus I. A dissolution test evaluates the rate and extent that a compound forms a solution under carefully controlled conditions. Within the context of regulatory approval, the USP dissolution test helps safeguard against the release of drug products that do not perform acceptably. USP Apparatus I (basket) and II (paddle) provide a platform to evaluate the *in vitro* performance of dosage forms using standardized conditions. These two apparatus, and associated procedures, have become widely used and accepted.

20. When measured in accordance with the United States Pharmacopeia ("USP") dissolution apparatus II, using 900 mL of USP buffer and having a pH of 6.8 at a paddle rotation speed of 200 rpm ("USP II Method"), the Myrbetriq® Tablets release 39% or less of mirabegron after 1.5 hours, and at least 75% mirabegron after 7 hours.

THE PATENTS-IN-SUIT

A. The '117 Patent

21. The United States Patent & Trademark Office ("PTO") duly and legally issued the '117 Patent, entitled "α-Form or β-Form Crystal of Acetanilide Derivative," on March 11, 2008. A true and correct copy of the '117 Patent is attached as **Exhibit A**.

22. The '117 Patent claims, *inter alia*, crystal forms of mirabegron.

23. The '117 Patent is listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with Myrbetriq® Tablets.

24. API is the record owner and assignee of the '117 Patent.

25. The '117 Patent will expire no earlier than November 4, 2023 and has pediatric exclusivity through May 4, 2024.

26. AICL is the exclusive licensee of the '117 Patent with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

27. APGD has contracted with AICL to, *inter alia*, clinically develop mirabegron, prepare and submit NDA No. 202611 for marketing approval of Myrbetriq® Tablets in the United States.

28. AICL has contracted with Astellas Pharma US, Inc., a subsidiary of API to, *inter alia*, market and sell Myrbetriq® Tablets, in the United States on its behalf.

29. Myrbetriq® Tablets are covered by one or more claims of the '117 Patent.

B. The '049 Patent

30. The PTO duly and legally issued the '049 Patent, entitled "α-Form or β-Form Crystal of Acetanilide Derivative," on July 19, 2011. A true and correct copy of the '049 Patent is attached as **Exhibit B**.

31. The '049 Patent claims, *inter alia*, pharmaceutical compositions comprising crystal forms of mirabegron and a pharmaceutically acceptable carrier.

32. The '049 Patent is listed in the "Orange Book in connection with Myrbetriq® Tablets.

33. API is the record owner and assignee of the '049 Patent.

34. The '049 Patent will expire no earlier than November 4, 2023 and has pediatric exclusivity through May 4, 2024.

35. AICL is the exclusive licensee of the '049 Patent with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

36. APGD has contracted with AICL to, *inter alia*, clinically develop mirabegron, prepare and submit NDA No. 202611 for marketing approval of Myrbetriq® Tablets in the United States.

37. AICL has contracted with Astellas Pharma US, Inc., a subsidiary of API to, *inter alia*, market and sell Myrbetriq® Tablets, in the United States on its behalf.

38. Myrbetriq® Tablets are covered by one or more claims of the '049 Patent.

C. The '474 Patent

39. The PTO duly and legally issued the '474 Patent, entitled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient," on September 16, 2014. A true and correct copy of the '474 Patent is attached as **Exhibit C**.

40. The '474 Patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron.

41. The '474 Patent is listed in the "Orange Book in connection with Myrbetriq® Tablets.

42. API is the record owner and assignee of the '474 Patent.

43. The '474 Patent will expire no earlier than November 4, 2023 and has pediatric exclusivity through May 4, 2024.

44. AICL is the exclusive licensee of the '474 Patent with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

45. APGD has contracted with AICL to, *inter alia*, clinically develop mirabegron, prepare and submit NDA No. 202611 for marketing approval of Myrbetriq® Tablets in the United States.

46. AICL has contracted with Astellas Pharma US, Inc., a subsidiary of API to, *inter alia*, market and sell Myrbetriq® Tablets, in the United States on its behalf.

47. Myrbetriq® Tablets are covered by one or more claims of the '474 Patent.

D. The '780 Patent

48. The PTO duly and legally issued the '780 Patent, entitled "Pharmaceutical Composition for Modified Release," on November 24, 2020. A true and correct copy of the '780 Patent is attached as **Exhibit D**.

49. The '780 Patent claims, *inter alia*, extended release hydrogel formulations of mirabegron with a certain dissolution profile.

50. The '780 Patent is listed in the "Orange Book in connection with Myrbetriq® Tablets.

51. API is the record owner and assignee of the '780 Patent.

52. The '780 Patent will expire no earlier than September 28, 2029 and has pediatric exclusivity through March 28, 2030.

53. AICL is the exclusive licensee of the '780 Patent with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

54. APGD has contracted with AICL to, *inter alia*, clinically develop mirabegron, prepare and submit NDA No. 202611 for marketing approval of Myrbetriq® Tablets in the United States.

55. AICL has contracted with Astellas Pharma US, Inc., a subsidiary of API to, *inter alia*, market and sell Myrbetriq® Tablets, in the United States on its behalf.

56. Myrbetriq® Tablets are covered by one or more claims of the '780 Patent.

E. The '872 Patent

57. The PTO duly and legally issued the '872 Patent, entitled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient," on April 29, 2014. A true and correct copy of the '872 Patent is attached as **Exhibit E**.

58. The '872 Patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron to adult subjects.

59. The '872 Patent also claims, *inter alia*, methods of treating overactive bladder by administering mirabegron, to non-adult subjects that are not suffering from diabetes.

60. The '872 Patent is listed in the "Orange Book in connection with Myrbetriq® Tablets.

61. API is the record owner and assignee of the '872 Patent.

62. The '872 Patent will expire no earlier than November 4, 2023 and has pediatric exclusivity through May 4, 2024.

63. AICL is the exclusive licensee of the '872 Patent with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

64. APGD has contracted with AICL to, *inter alia*, clinically develop mirabegron, prepare and submit NDA No. 202611 for marketing approval of Myrbetriq® Tablets in the United States.

65. AICL has contracted with Astellas Pharma US, Inc., a subsidiary of API to, *inter alia*, market and sell Myrbetriq® Tablets, in the United States on its behalf.

66. Myrbetriq® Tablets are covered by one or more claims of the '872 Patent.

MIRABEGRON ANDA FILERS

67. In June 2013, FDA issued a notice in the Federal Register (78 Fed. Reg. 37230 at 31 (June 20, 2013)) regarding bioequivalence guidance to be published on its website for mirabegron ANDAs. On its website, FDA lists the following dissolution requirements for mirabegron ANDA filers in order to establish bioequivalence with Myrbetriq® Tablets ("Mirabegron Bioequivalence Guidance"):

Drug Name	Dosage Form	USP Apparatus	Speed (RPMs)	Medium	Volume (mL)	Recommended Sampling Times (minutes)	Date Updated
Mirabegron	Tablet (Extended Release)	I (Basket)	100	Phosphate Buffer, pH 6.8	900	1, 3, 5, 7, 8.5, 10 and 12 hours	05/09/2013

68. On information and belief, each mirabegron ANDA filer will be required to meet this dissolution method, or an equivalent dissolution method, to meet its bioequivalence requirements for its proposed ANDA product using Myrbetriq® Tablets as the reference standard.

On information and belief, a proposed mirabegron ANDA product will have equivalent dissolution properties to Myrbetriq® Tablets as measured by USP Apparatus I and II.

CLAIMS FOR RELIEF

COUNT I: DIRECT INFRINGEMENT OF THE '117 PATENT BY ALKEM

69. Plaintiffs incorporate by reference and reallege paragraphs 1 through 68 above as though fully restated herein.

70. Alkem, by filing ANDA No. 215948, has necessarily represented to FDA that, upon approval, Alkem's ANDA Product will be administered to treat overactive bladder in accordance with its label and have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

71. Alkem has indicated, including *inter alia* via Alkem's Notice Letter, its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Alkem's ANDA Product prior to the expiration of the '117 Patent's patent term and pediatric exclusivity period.

72. In Alkem's Notice Letter, Alkem does not deny that Alkem's ANDA Product is covered by one or more claims of the '117 Patent.

73. Alkem's submission of ANDA No. 215948 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Alkem's ANDA Product, prior to the expiration of the '117 Patent, constitutes infringement of one or more of the claims of the '117 Patent under 35 U.S.C. § 271(e)(2)(A).

74. Unless Alkem is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alkem's infringement of the '117 Patent. Plaintiffs do not have an adequate remedy at law.

75. Plaintiffs are commencing this action within 45 days of receiving Alkem's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT II: DIRECT INFRINGEMENT OF THE '049 PATENT BY ALKEM

76. Plaintiffs incorporate by reference and reallege paragraphs 1 through 75 above as though fully restated herein.

77. Alkem, by filing ANDA No. 215948, has necessarily represented to FDA that, upon approval, Alkem's ANDA Product will be administered to treat overactive bladder in accordance with its label and have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

78. Alkem has indicated, including *inter alia* via Alkem's Notice Letter, its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Alkem's ANDA Product prior to the expiration of the '049 Patent's patent term and pediatric exclusivity period.

79. In Alkem's Notice Letter, Alkem does not deny that Alkem's ANDA Product is covered by one or more claims of the '049 Patent.

80. Alkem's submission of ANDA No. 215948 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Alkem's ANDA Product, prior to the expiration of the '049 Patent, constitutes infringement of one or more of the claims of the '049 Patent under 35 U.S.C. § 271(e)(2)(A).

81. Unless Alkem is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alkem's infringement of the '049 Patent. Plaintiffs do not have an adequate remedy at law.

82. Plaintiffs are commencing this action within 45 days of receiving Alkem's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT III: DIRECT INFRINGEMENT OF THE '474 PATENT BY ALKEM

83. Plaintiffs incorporate by reference and reallege paragraphs 1 through 82 above as though fully restated herein.

84. Alkem, by filing ANDA No. 215948, has necessarily represented to FDA that, upon approval, Alkem's ANDA Product will be administered to treat overactive bladder in accordance with its label and have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

85. Alkem has indicated, including *inter alia* via Alkem's Notice Letter, its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Alkem's ANDA Product prior to the expiration of the '474 Patent's patent term and pediatric exclusivity period.

86. In Alkem's Notice Letter, Alkem does not deny that Alkem's ANDA Product is covered by one or more claims of the '474 Patent.

87. Alkem's submission of ANDA No. 215948 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Alkem's ANDA Product, prior to the expiration of the '474 Patent, constitutes infringement of one or more of the claims of the '474 Patent under 35 U.S.C. § 271(e)(2)(A).

88. Unless Alkem is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alkem's infringement of the '474 Patent. Plaintiffs do not have an adequate remedy at law.

89. Plaintiffs are commencing this action within 45 days of receiving Alkem's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT IV: INDUCEMENT TO INFRINGE THE '474 PATENT BY ALKEM

90. Plaintiffs incorporate by reference and reallege paragraphs 1 through 89 above as though fully restated herein.

91. Alkem has knowledge of the '474 Patent.

92. If Alkem's ANDA Product is approved by FDA and is sold by Alkem, its use by healthcare providers and/or patients will directly infringe one or more claims of the '474 Patent.

93. Alkem's proposed label for its ANDA Product explicitly instructs healthcare providers and/or patients to use Alkem's ANDA Product in a manner that will directly infringe one or more claims of the '474 Patent.

94. Any use of Alkem's ANDA Product by patients will be performed at the direction and control of healthcare providers treating overactive bladder, who in turn are instructed by Alkem in its proposed label for its ANDA Product.

95. If Alkem's ANDA Product is approved by FDA, Alkem will actively induce others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '474 Patent. Alkem has acted with knowledge that the induced acts would constitute infringement of the '474 Patent.

96. Alkem specifically intends to cause direct infringement by others, e.g., healthcare providers and/or patients.

97. If and when FDA approves ANDA No. 215948, Alkem will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Alkem's proposed label, to use Alkem's ANDA Product in a manner that directly infringes one or more claims of the '474 Patent. Thus, Alkem will aid, abet, urge, and/or encourage others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '474 Patent, and Alkem will affirmatively and specifically intend to cause direct infringement.

98. Alkem's actions will constitute inducement of infringement of the '474 Patent pursuant to 35 U.S.C § 271(b).

99. Unless Alkem is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alkem's infringement of the '474 Patent. Plaintiffs do not have an adequate remedy at law.

100. Plaintiffs are commencing this action within 45 days of receiving Alkem's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT V: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT BY ALKEM

101. Plaintiffs incorporate by reference and reallege paragraphs 1 through 100 above as though fully restated herein.

102. If ANDA No. 215948 is approved by the FDA, Alkem intends to and will offer to sell, sell, and/or import into the United States Alkem's ANDA Product.

103. Alkem's ANDA Product constitutes a material part of the inventions covered by the claims of the '474 Patent and has no substantial non-infringing uses.

104. On information and belief, Alkem has had and continues to have knowledge that Alkem's ANDA Product is especially adapted for a use that infringes one or more claims of the '474 Patent.

105. On information and belief, Alkem has had and continues to have knowledge that there is no substantial non-infringing use for Alkem's ANDA Product.

106. Alkem's actions will constitute contributory infringement of the '474 Patent pursuant to 35 U.S.C. § 271(c).

107. Unless Alkem is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alkem's infringement of the '474 Patent. Plaintiffs do not have an adequate remedy at law.

108. Plaintiffs are commencing this action within 45 days of receiving Alkem's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT VI: DIRECT INFRINGEMENT OF THE '780 PATENT BY ALKEM

109. Plaintiffs incorporate by reference and reallege paragraphs 1 through 108 above as though fully restated herein.

110. Alkem, by filing ANDA No. 215948, has necessarily represented to FDA that, upon approval, Alkem's ANDA Product will be administered to treat overactive bladder in accordance with its label and have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

111. Alkem has indicated, including *inter alia* via Alkem's Notice Letter, its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Alkem's ANDA Product prior to the expiration of the '780 Patent's patent term and pediatric exclusivity period.

112. On information and belief, and as required by the Mirabegron Bioequivalence Guidance, Alkem uses the dissolution method (or its equivalent) to establish Alkem's ANDA Product is bioequivalent to Myrbetriq® Tablets. On information and belief, Alkem's ANDA Product will have equivalent dissolution properties, as measured by USP Apparatus I and II, to Myrbetriq® Tablets, which uses a hydrogel formulation. On information and belief, because of the dissolution requirements contained within the Mirabegron Bioequivalence Guidance, including the use of Myrbetriq® Tablets as the reference standard, Alkem's ANDA Product uses a hydrogel formulation, the same as or equivalent to the Myrbetriq® Tablets formulation, that is covered by one or more claims of the '780 Patent.

113. On information and belief, Alkem relied on, *inter alia*, Alkem's dissolution data to conclude that Alkem's ANDA Product is bioequivalent to Astellas's Myrbetriq® Tablets.

114. In Alkem's Notice Letter, Alkem does not deny that Alkem's ANDA Product is covered by one or more claims of the '780 Patent.

115. Alkem's submission of ANDA No. 215948 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Alkem's ANDA Product, prior to the expiration of the '780 Patent, constitutes infringement of one or more of the claims of the '780 Patent under 35 U.S.C. § 271(e)(2)(A).

116. Unless Alkem is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alkem's infringement of the '780 Patent. Plaintiffs do not have an adequate remedy at law.

117. Plaintiffs are commencing this action within 45 days of receiving Alkem's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT VII: DIRECT INFRINGEMENT OF THE '872 PATENT BY ALKEM

118. Plaintiffs incorporate by reference and reallege paragraphs 1 through 117 above as though fully restated herein.

119. Alkem, by filing ANDA No. 215948, has necessarily represented to FDA that, upon approval, Alkem's ANDA Product will be administered to treat overactive bladder in accordance with its label and have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

120. Alkem has indicated, including *inter alia* via Alkem's Notice Letter, its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Alkem's ANDA Product prior to the expiration of the '872 Patent's patent term and pediatric exclusivity period.

121. In Alkem's Notice Letter, Alkem does not deny that Alkem's ANDA Product is covered by one or more claims of the '872 Patent.

122. Alkem's submission of ANDA No. 215948 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Alkem's ANDA Product, prior to the expiration of the '872 Patent, constitutes infringement of one or more of the claims of the '872 Patent under 35 U.S.C. § 271(e)(2)(A).

123. Unless Alkem is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alkem's infringement of the '872 Patent. Plaintiffs do not have an adequate remedy at law.

124. Plaintiffs are commencing this action within 45 days of receiving Alkem's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT VIII: INDUCEMENT TO INFRINGE THE '872 PATENT BY ALKEM

125. Plaintiffs incorporate by reference and reallege paragraphs 1 through 124 above as though fully restated herein.

126. Alkem has knowledge of the '872 Patent.

127. If Alkem's ANDA Product is approved by FDA and is sold by Alkem, its use by healthcare providers and/or patients will directly infringe one or more claims of the '872 Patent.

128. Alkem's proposed label for its ANDA Product explicitly instructs healthcare providers and/or patients to use Alkem's ANDA Product in a manner that will directly infringe one or more claims of the '872 Patent.

129. Any use of Alkem's ANDA Product by patients will be performed at the direction and control of healthcare providers treating overactive bladder, who in turn are instructed by Alkem in its proposed label for its ANDA Product.

130. If Alkem's ANDA Product is approved by FDA, Alkem will actively induce others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the

'872 Patent. Alkem has acted with knowledge that the induced acts would constitute infringement of the '872 Patent.

131. Alkem specifically intends to cause direct infringement by others, e.g., healthcare providers and/or patients.

132. If and when FDA approves ANDA No. 215948, Alkem will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Alkem's proposed label, to use Alkem's ANDA Product in a manner that directly infringes one or more claims of the '872 Patent. Thus, Alkem will aid, abet, urge, and/or encourage others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '872 Patent, and Alkem will affirmatively and specifically intend to cause direct infringement.

133. Alkem's actions will constitute inducement of infringement of the '872 Patent pursuant to 35 U.S.C § 271(b).

134. Unless Alkem is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alkem's infringement of the '872 Patent. Plaintiffs do not have an adequate remedy at law.

135. Plaintiffs are commencing this action within 45 days of receiving Alkem's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT IX: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT BY ALKEM

136. Plaintiffs incorporate by reference and reallege paragraphs 1 through 135 above as though fully restated herein.

137. If ANDA No. 215948 is approved by the FDA, Alkem intends to and will offer to sell, sell, and/or import into the United States Alkem's ANDA Product.

138. Alkem's ANDA Product constitutes a material part of the inventions covered by the claims of the '872 Patent and has no substantial non-infringing uses.

139. On information and belief, Alkem has had and continues to have knowledge that Alkem's ANDA Product is especially adapted for a use that infringes one or more claims of the '872 Patent.

140. On information and belief, Alkem has had and continues to have knowledge that there is no substantial non-infringing use for Alkem's ANDA Product.

141. Alkem's actions will constitute contributory infringement of the '872 Patent pursuant to 35 U.S.C. § 271(c).

142. Unless Alkem is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Alkem's infringement of the '872 Patent. Plaintiffs do not have an adequate remedy at law.

143. Plaintiffs are commencing this action within 45 days of receiving Alkem's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs API, AICL, and APGD, pray for a judgment in their favor and against Alkem, and respectfully request the following relief:

A. A judgment that Alkem's submission and maintenance of its ANDA (i.e., the Alkem ANDA) constituted an act of infringement of the Patents-in-suit (i.e., the '117 Patent, the '049 Patent, the '474 Patent, the '780 Patent, and the '872 Patent);

B. A judgment (or a declaration) that Alkem's making, using, offering to sell, or selling in the United States or importing into the United States of its Proposed ANDA Product (i.e., Alkem's ANDA Product) will infringe the Patents-in-suit;

C. A permanent injunction restraining and enjoining Alkem, its affiliates, subsidiaries, officers, agents, attorneys and employees, and those acting in privity or concert with Alkem, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or

importation into the United States, of its Proposed ANDA Product until the expiration of the Patents-in-suit, including their pediatric exclusivity periods and any other extensions and/or periods of exclusivity to which Plaintiffs and/or the Patents-in-suit are or become entitled;

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Alkem's ANDA shall be a date that is not earlier than the expiration date of the Patents-in-suit, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the Patents-in-suit are or become entitled;

E. Damages, including monetary and other relief, to Plaintiffs if Alkem engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of its Proposed ANDA Product, prior to the expiration date of the Patents-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

F. A declaration that this case is "exceptional" within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: July 6, 2021

MCCARTER & ENGLISH, LLP

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