**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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|---|---|---|
| ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC., | ) | |
| Plaintiffs, | ) | C.A. No. _____ |
| v. | ) | |
| CREEKWOOD PHARMACEUTICALS LLC, | ) | |
| 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:

**PARTIES**

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

1. 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.

2. 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.

3. 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 2375 Waterview Drive, Northbrook, Illinois 60062. APGD is a subsidiary of Plaintiff API.

**B. Creekwood Pharmaceuticals LLC ("Creekwood" or "Defendant")**

4. On information and belief, Creekwood is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 1130 Route 46, Suite 21, Parsippany, New Jersey 07054-2148.

5. On information and belief, Creekwood is in the business of, *inter alia*, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in this judicial district.

6. By a letter dated November 22, 2024 ("Creekwood's Notice Letter"), Creekwood notified Astellas that Creekwood had submitted to the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 219599 for mirabegron extended-release oral tablets, 25 mg and 50 mg ("Creekwood ANDA"), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 25 mg and 50 mg strengths ("Creekwood's ANDA Products"). On information and belief, the purpose of Creekwood's submission of the Creekwood ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Creekwood's ANDA Products prior to March 28, 2030.

7. In Creekwood's Notice Letter, Creekwood notified Astellas that as part of the Creekwood ANDA, Creekwood 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), i.e., a Paragraph IV certification, with respect to U.S. Patent Nos. 10,842,780 (the "'780 Patent"), 11,707,451 (the "'451 Patent"), 12,059,409 (the "'409 Patent") and 12,097,189 (the "'189 Patent"), four of the then-listed patents in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), asserting that they are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Creekwood's ANDA Products.

## NATURE OF ACTION

8. This is an action for patent infringement of United States Patent Nos. 10,842,780, 11,707,451, 12,059,409 and 12,097,189 (collectively, "the Patents-in-Suit") arising under the United States patent laws, Title 35, United States Code. This action relates to the Creekwood ANDA submitted under Section 505(j) of the FDCA, 21 U.S.C. § 355(j), which seeks FDA approval to market generic pharmaceutical products.

## JURISDICTION AND VENUE

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

10. This Court has personal jurisdiction over Defendant because, *inter alia*, it has committed, aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in filing the Creekwood ANDA that has led to foreseeable harm and injury to Plaintiffs, and will imminently commit, aid, abet, contribute to, or participate in the commission of a tortious act of patent infringement by selling each of the Creekwood ANDA Products throughout the United States and in this judicial district, which will lead to foreseeable harm and injury to Plaintiffs.

11. This Court also has personal jurisdiction over Defendant because its affiliations with the State of Delaware, by virtue of its incorporation in Delaware, are so continuous and systematic as to render Defendant essentially at home in this forum.

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

13. 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).

## THE PATENTS-IN-SUIT

### C. The ’780 Patent

14. The United States Patent & Trademark Office (“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 A**.

15. The ’780 Patent generally claims tablet formulations of “10 mg to 100 mg” of mirabegron, comprising a “sustained release hydrogel-forming formulation” that further comprises “a hydrogel-forming polymer having an average molecular weight of 100,000 to 8,000,000” and “an additive having a water solubility of at least 0.1 g/mL at 20±5 °C” and possessing certain dissolution profiles.

16. API is the record owner and assignee of the ’780 Patent. The ’780 Patent will expire no earlier than September 28, 2029.

17. The ’780 Patent retains FDA pediatric exclusivity through midnight on March 28, 2030.

18. The ’780 Patent is listed in the FDA’s Orange Book in connection with NDA No. 202611 as covering Myrbetriq® Tablets.

### D. The ’409 Patent

19. The United States Patent & Trademark Office (“PTO”) duly and legally issued the ’409 Patent, entitled “Pharmaceutical Composition for Modified Release,” on August 13, 2024. A true and correct copy of the ’409 Patent is attached as **Exhibit B**.

20. The ’409 Patent generally claims tablet formulations of mirabegron comprising certain excipients and possessing certain dissolution profiles. Independent Claim 1 of the ’409 Patent recites “[a] tablet comprising 10 mg to 200 mg of [mirabegron], or a pharmaceutically acceptable salt thereof, in a sustained release hydrogel-forming formulation comprising a hydrogel-forming polymer having an average molecular weight of 200,000 to 7,000,000 and an additive having a water solubility of at least 0.1 g/mL at 20+5 [sic] °C.” (A Request for a Certificate

of Correction (attached as **Exhibit E**) was filed on August 26, 2024 requesting, *inter alia*, a correction of Claim 1 to "20±5 °C".)

21. API is the record owner and assignee of the '409 Patent. The '409 Patent will expire no earlier than September 28, 2029.

22. The '409 Patent is listed in the FDA's Orange Book in connection with NDA No. 202611 as covering Myrbetriq® Tablets.

**E. The '451 Patent**

23. The PTO duly and legally issued the '451 Patent, entitled "Pharmaceutical Composition for Modified Release," on July 25, 2023. A true and correct copy of the '451 Patent is attached as **Exhibit C**.

24. The '451 Patent generally claims a method for treating overactive bladder such that the treating is with a reduced food effect, comprising administering orally a tablet comprising "10 mg to 200 mg" or "25 mg" or "50 mg" mirabegron in a sustained release formulation that further comprises a carrier and provides a continuous drug release for at least 4 hours after oral administration, wherein the reduced food effect is compared to that after oral administration of an immediate release formulation of mirabegron.

25. API is the record owner and assignee of the '451 Patent.

26. The '451 Patent will expire no earlier than September 28, 2029.

27. The '451 Patent retains FDA pediatric exclusivity through midnight on March 28, 2030.

28. The '451 Patent is listed in the Orange Book in connection with NDA No. 202611 as covering Myrbetriq® Tablets.

**F. The ’189 Patent**

29. The PTO duly and legally issued the ’189 Patent, entitled “Pharmaceutical Composition for Modified Release,” on September 24, 2024. A true and correct copy of the ’189 Patent is attached as **Exhibit D**.

30. The ’189 Patent generally claims methods for treating overactive bladder such that the treating is with a reduced food effect, comprising administering orally to a subject in need thereof a tablet comprising “25 mg” or “50 mg” mirabegron in a sustained release hydrogel-forming formulation that further comprises a carrier and provides a continuous drug release for at least 4 hours after oral administration, wherein the reduced food effect is compared to that after oral administration of an immediate release capsule formulation comprising mirabegron and is a difference in a rate of decrease of $C_{max}$ of 10% or more.

31. API is the record owner and assignee of the ’189 Patent.

32. The ’189 Patent will expire no earlier than September 28, 2029.

33. The ’189 Patent is listed in the Orange Book in connection with NDA No. 202611 as covering Myrbetriq® Tablets.

**MYRBETRIQ® TABLETS**

34. APGD holds approved New Drug Application (“NDA”) No. 202611 for Myrbetriq® extended-release tablets (“Myrbetriq® Tablets”), available in 25 mg (“25 mg Myrbetriq® Product”) and 50 mg (“50 mg Myrbetriq® Product”) strengths, which contain the active ingredient, mirabegron. The FDA approved NDA No. 202611 on June 28, 2012 for both the 25 mg Myrbetriq ® Product and the 50 mg Myrbetriq® Product.

35. API is the recorded assignee for each of the Patents-in-Suit.

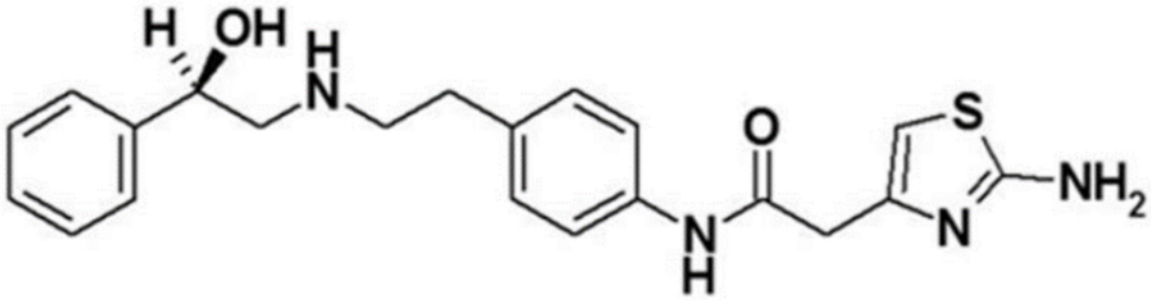
36. AICL is the exclusive licensee of each of the Patents-in-Suit with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms, which contain mirabegron as the active ingredient in the United States.

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

38. 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 AICL's behalf.

39. Myrbetriq® Tablets are covered by one or more claims of each of the Patents-in-Suit.

40. 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:




41. The FDA approved Prescribing Information for Myrbetriq® ("Myrbetriq® Label") states that Myrbetriq® Tablets are indicated for the treatment of overactive bladder. A true and correct copy of the Myrbetriq® Label, revised April 2021, available at https://www.astellas.us/docs/myrbetriq_wpi.pdf, is attached as **Exhibit F**.

42. Myrbetriq® Tablets comprise sustained release hydrogel-forming formulations of Myrbetriq® Tablets in a carrier, i.e., contain either 25 mg or 50 mg of mirabegron in extended-release tablets, and provide a continuous drug release of mirabegron for at least 4 hours after oral administration, as required by one or more claims of the '451 Patent and the '189 Patent.

43. Myrbetriq® Tablets comprise polyethylene oxide and polyethylene glycol, which function as a hydrogel-forming polymer and an additive, respectively, as required by one or more claims of the ’780 Patent and the ’409 Patent.

44. The polyethylene oxide in Myrbetriq® Tablets has an average molecular weight of 200,000 to 7,000,000, as required by one or more claims of the ’780 Patent and the ’409 Patent.

45. The polyethylene glycol in Myrbetriq® Tablets has a water solubility of at least 0.1 g/mL at 20±5 ºC, as required by one or more claims of the ’780 Patent and the ’409 Patent.

46. 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.

47. When measured in accordance with the 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, the Myrbetriq® Tablets release 39% or less of mirabegron after 1.5 hours, and at least 75% of mirabegron after 7 hours, as required by one or more claims of the ’780 Patent and the ’409 Patent.

48. When an immediate-release capsule formulation of mirabegron is administered orally, it exhibits a food effect. (**Exhibit C** (’451 Patent) at 1:50–58, 44:27–31; **Exhibit D** (’189 Patent) at 1:55–63, 45:22–26.)

49. Myrbetriq® Tablets provide a reduced food effect when compared to the food effect after oral administration of an immediate release mirabegron formulation, as required by one or more claims of the ’451 Patent and the ’189 Patent.

50. The reduced food effect provided by Myrbetriq® Tablets, when compared to that after oral administration of an immediate release capsule of mirabegron, is a difference in a rate of decrease of $C_{max}$ of 10% or more, as required by one or more claims of the ’189 Patent.

51. When used in accordance with the instructions of the Myrbetriq® Label, the sustained release hydrogel-forming formulations of the Myrbetriq® Tablets provide a continuous drug release for at least 4 hours after oral administration, as recited in the claims of the ’451 Patent and the ’189 Patent.

52. Myrbetriq® Tablets are covered by one or more claims of the ’780 Patent and the ’409 Patent.

53. The use of the Myrbetriq® Tablets to treat overactive bladder meets each claim limitation of one or more claims of the ’451 Patent and the ’189 Patent.

## THE CREEKWOOD ANDA

54. Under Section 505(j)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(iv), an ANDA filer must show that its ANDA product is bioequivalent to the Reference Listed Drug for that ANDA product.

55. In June 2013, FDA issued a notice in the Federal Register (78 Fed. Reg. 37230 at 30–31 (June 20, 2013)) regarding bioequivalence guidance to be published on its website for mirabegron ANDAs. This guidance (“the Mirabegron Guidance”) requires each mirabegron ANDA filer to complete certain comparative bioequivalence studies against Myrbetriq® Tablets, two in the fed state (i.e., with food) and one in the fasting state (i.e., without food).

56. On information and belief, Creekwood was required to run the recommended studies listed in the Mirabegron Guidance in comparison to Myrbetriq Tablets® to meet its bioequivalence requirements for its proposed ANDA product. The Mirabegron Guidance sets a 90% confidence interval “sameness” requirement to establish bioequivalence to Myrbetriq® Tablets.

57. The Mirabegron Guidance also required Creekwood to conduct comparative dissolution against the Myrbetriq® Tablets. On its website, FDA lists the following dissolution requirements for mirabegron ANDA filers in order to establish bioequivalence with Myrbetriq® Tablets:

| 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 |

58. On information and belief, Creekwood was 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.

59. No later than November 22, 2024, Creekwood submitted to the FDA the Creekwood ANDA for Creekwood's ANDA Products seeking authorization to commercially manufacture, use, import, offer to sell, or sell Creekwood's ANDA Products in the United States.

60. Creekwood, via Creekwood's Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale marketing, distributing, and/or importation of Creekwood's ANDA Products prior to expiration of Plaintiffs' Orange Book-listed patents.

61. By filing the Creekwood ANDA, Creekwood has necessarily represented to the FDA that, upon approval, Creekwood's ANDA Products will have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

62. On information and belief, Creekwood was required to run the recommended studies listed in the Mirabegron Guidance in comparison to Myrbetriq® Tablets to meet its bioequivalence requirements for Creekwood's ANDA Products. The Mirabegron Guidance

required Creekwood to set a 90% confidence interval "sameness" requirement to establish bioequivalence to Myrbetriq® Tablets. The Mirabegron Guidance also required Creekwood to conduct comparative dissolution studies against Myrbetriq® Tablets. On information and belief, Creekwood complied with the requirements of the Mirabegron Guidance to establish bioequivalence and showed that Creekwood's ANDA Products are bioequivalent to Myrbetriq® Tablets.

63. On information and belief, Creekwood's actions relating to the Creekwood ANDA were done by and for the benefit of Creekwood.

64. Under Section 505(j)(2)(A)(v) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(v), the prescribing information of Creekwood's ANDA Products is required to substantively copy that of Myrbetriq® Tablets.

65. On information and belief, the proposed prescribing information for Creekwood's ANDA Products ("Creekwood's Label") will be substantially identical to that of Myrbetriq® Tablets.

66. On information and belief, Creekwood will include Creekwood's Label with Creekwood's ANDA Products.

67. On information and belief, Creekwood's Label will indicate that Creekwood's ANDA Products are approved for treating overactive bladder. Indeed, Creekwood's Notice Letter indicated that its mirabegron extended-release tablets, 25 mg and 50 mg, are indicated for the treatment of: Overactive bladder (OAB) in adult patients.

68. On information and belief, Creekwood's Label will instruct that Creekwood's ANDA Products can be taken with or without food.

69. On information and belief, Creekwood's Label will instruct and encourage healthcare professionals to practice the claimed methods of the '451 Patent and the '189 Patent.

## CLAIMS FOR RELIEF

## COUNT I: INFRINGEMENT OF THE '780 PATENT

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

71. On information and belief, Creekwood intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Creekwood's ANDA Products upon final approval of the Creekwood ANDA and prior to the expiration of the pediatric exclusivity associated with the '780 Patent, i.e., March 28, 2030.

72. On information and belief, the commercial manufacture, use, offer for sale, or sale of Creekwood's ANDA Products would infringe the '780 Patent. Creekwood's submission of ANDA No. 219599 seeking approval to engage in the commercial manufacture, use, offer for sale, or sale of Creekwood's ANDA Products, prior to the expiration of the '780 Patent, therefore constitutes infringement of one or more claims of the '780 Patent under 35 U.S.C. § 271(e)(2)(A). *See Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 330–331 (D. Del. 2019); *see also Novartis Pharms. Corp. v. Alembic Pharms. Ltd.*, 2023 WL6387975, *4 (D. Del. Sep. 29, 2023).

73. Creekwood, via Creekwood's Notice Letter, has indicated that Creekwood's ANDA Products contain either 25 mg or 50 mg of mirabegron in extended-release tablets, as required by one or more claims of the '780 Patent.

74. On information and belief, to match the Myrbetriq® Tablets dissolution profile to establish bioequivalence, Creekwood copied from the Myrbetriq® Tablets formulation.

75. On information and belief, and as required by the Mirabegron Guidance, Creekwood used the dissolution method (or its equivalent) to establish that Creekwood's ANDA Products are bioequivalent to Myrbetriq® Tablets. On information and belief, Creekwood's ANDA Products will have equivalent dissolution properties, as measured by USP Apparatus I and II, to Myrbetriq® Tablets, which use sustained release hydrogel-forming formulations, and thus,

Creekwood's ANDA Products will meet the dissolution limitation of the '780 Patent. On information and belief, because of the dissolution requirements contained within the Mirabegron Guidance, including the use of Myrbetriq® Tablets as the reference standard, Creekwood's ANDA Products use a sustained release hydrogel-forming formulation, the same as or equivalent to the Myrbetriq® Tablets formulation, that is covered by one or more claims of the '780 Patent.

76. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Creekwood's ANDA Products would infringe one or more claims of the '780 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a).

77. On information and belief, if Creekwood's ANDA Products are sold, marketed, distributed, and/or imported in the United States, Creekwood knows and intends that physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use Creekwood's ANDA Products according to Creekwood's instructions and/or Creekwood's Label for the treatment of overactive bladder, and will therefore induce infringement of at least one or more claims of the '780 Patent with the requisite intent under 35 U.S.C. § 271(b).

78. Unless Creekwood is enjoined by the Court, Astellas will be substantially and irreparably harmed by Creekwood's infringement of the '780 Patent. Astellas does not have an adequate remedy at law.

## COUNT II: INFRINGEMENT OF THE '409 PATENT

79. Plaintiffs incorporate by reference and reallege paragraphs 1 through 78 above as though fully restated herein.

80. On information and belief, Creekwood intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Creekwood's ANDA Products upon final approval of the Creekwood ANDA and prior to the expiration of the '409 Patent.

81. On information and belief, the commercial manufacture, use, offer for sale, or sale of Creekwood's ANDA Products would infringe the '409 Patent. Creekwood's submission of

ANDA No. 219599 seeking approval to engage in the commercial manufacture, use, offer for sale, or sale of Creekwood's ANDA Products, prior to the expiration of the '409 Patent, therefore constitutes infringement of one or more claims of the '409 Patent under 35 U.S.C. § 271(e)(2)(A). *See Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 330–331 (D. Del. 2019); *see also Novartis Pharms. Corp. v. Alembic Pharms. Ltd.*, 2023 WL6387975, *4 (D. Del. Sep. 29, 2023).

82. Creekwood, via Creekwood's Notice Letter, has indicated that Creekwood's ANDA Products contain either 25 mg or 50 mg of mirabegron in extended-release tablets, as required by one or more claims of the '409 Patent.

83. On information and belief, to match the Myrbetriq® Tablets dissolution profile to establish bioequivalence, Creekwood copied from the Myrbetriq® Tablets formulation.

84. On information and belief, and as required by the Mirabegron Guidance, Creekwood used the dissolution method (or its equivalent) to establish that Creekwood's ANDA Products are bioequivalent to Myrbetriq® Tablets. On information and belief, Creekwood's ANDA Products will have equivalent dissolution properties, as measured by USP Apparatus I and II, to Myrbetriq® Tablets, which use sustained release hydrogel-forming formulations, and thus, Creekwood's ANDA Products will meet the dissolution limitation of the '409 Patent. On information and belief, because of the dissolution requirements contained within the Mirabegron Guidance, including the use of Myrbetriq® Tablets as the reference standard, Creekwood's ANDA Products use a sustained release hydrogel-forming formulation, the same as or equivalent to the Myrbetriq® Tablets formulation, that is covered by one or more claims of the '409 Patent.

85. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Creekwood's ANDA Products would infringe one or more claims of the '409 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a).

86. Unless Creekwood is enjoined by the Court, Astellas will be substantially and irreparably harmed by Creekwood's infringement of the '409 Patent. Astellas does not have an adequate remedy at law.

**COUNT III: INFRINGEMENT OF THE ’451 PATENT**

87. Plaintiffs incorporate by reference and reallege paragraphs 1 through 86 above as though fully restated herein.

88. On information and belief, Creekwood intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Creekwood’s ANDA Products upon final approval of the Creekwood ANDA and prior to the expiration of the pediatric exclusivity associated with the ’451 Patent, i.e., March 28, 2030.

89. Creekwood’s submission of ANDA No. 219599 seeking approval to engage in the commercial manufacture, use, offer for sale, or sale of Creekwood’s ANDA Products, prior to the expiration of the ’451 Patent, constitutes infringement of one or more claims of the ’451 Patent under 35 U.S.C. § 271(e)(2)(A).

90. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Creekwood’s ANDA Products would infringe one or more claims of the ’451 Patent, or their equivalents, at least under 35 U.S.C. §§ 271 (b) and/or (c). In the factual and legal bases for Creekwood’s Paragraph IV certification made in connection with Creekwood’s ANDA, Creekwood did not contend that the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Creekwood’s ANDA Products would not infringe one or more claims of the ’451 Patent.

91. Creekwood, via Creekwood’s Notice Letter, has indicated that Creekwood’s ANDA Products contain either 25 mg or 50 mg of mirabegron in extended-release tablets, as required by one or more claims of the ’451 Patent.

92. On information and belief, Creekwood’s ANDA Products comprise sustained release hydrogel-forming formulations of mirabegron in a carrier, i.e., contain either 25 mg or 50 mg of mirabegron in extended-release tablets, as required by one or more claims of the ’451 Patent.

93. On information and belief, Creekwood followed the Mirabegron Guidance and conducted bioequivalence studies under fasting and fed conditions in comparison with Myrbetriq®

Tablets to establish bioequivalence, and Creekwood also followed the Mirabegron Guidance by conducting comparative dissolution testing of Creekwood's ANDA Products against Myrbetriq® Tablets to establish bioequivalence. On information and belief, Creekwood's ANDA Products will have equivalent dissolution properties, and hence equivalent drug release properties, to Myrbetriq® Tablets. Accordingly, because Myrbetriq® Tablets provide a continuous drug release for at least 4 hours after oral administration, Creekwood's ANDA Products likewise also provide a continuous drug release for at least 4 hours after oral administration, as required by the claims of the '451 Patent. Accordingly, because Myrbetriq® Tablets exhibit a reduced food effect, as compared to an immediate release formulation of mirabegron, on information and belief, Creekwood's ANDA Products likewise reduce the food effect, as required by the claims of the '451 Patent.

94. On information and belief, if Creekwood's ANDA Products are sold, marketed, distributed, and/or imported in the United States, Creekwood knows and intends that physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use Creekwood's ANDA Products according to Creekwood's instructions and/or Creekwood's Label in an infringing manner, and will therefore induce infringement of at least one or more claims of the '451 Patent with the requisite intent under 35 U.S.C. § 271(b).

95. On information and belief, if Creekwood's ANDA Products are sold, marketed, distributed, and/or imported in the United States, Creekwood will sell or offer to sell generic mirabegron extended-release tablets with provided instructions and/or Creekwood's Label in an infringing manner, wherein Creekwood's ANDA Products are a material part of the claimed invention, wherein Creekwood knows that physicians will prescribe, healthcare providers will administer, and/or patients will use Creekwood's ANDA Products in accordance with Creekwood's provided instructions and/or Creekwood's Label, wherein such use will directly infringe at least one or more claims of the '451 Patent, and wherein generic mirabegron extended-release tablets are not staple articles or commodities of commerce suitable for substantial non-

infringing use. On information and belief, Creekwood will thus contribute to the infringement of at least one or more claims of the ’451 Patent under 35 U.S.C. § 271(c).

96. At least by the filing date of this Complaint, Creekwood will have actual knowledge of the ’451 Patent.

97. Unless Creekwood’s marketing and sale of Creekwood’s ANDA Products prior to the expiration of the ’451 Patent and all other relevant activities are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Creekwood’s infringement of the ’451 Patent. Plaintiffs do not have an adequate remedy at law.

**COUNT IV: INFRINGEMENT OF THE ’189 PATENT**

98. Plaintiffs incorporate by reference and reallege paragraphs 1 through 97 above as though fully restated herein.

99. On information and belief, Creekwood intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Creekwood’s ANDA Products upon final approval of the Creekwood ANDA and prior to the expiration of the ’189 Patent.

100. Creekwood’s submission of ANDA No. 219599 seeking approval to engage in the commercial manufacture, use, offer for sale, or sale of Creekwood’s ANDA Products, prior to the expiration of the ’189 Patent, constitutes infringement of one or more claims of the ’189 Patent under 35 U.S.C. § 271(e)(2)(A).

101. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Creekwood’s ANDA Products would infringe one or more claims of the ’189 Patent, or their equivalents, at least under 35 U.S.C. §§ 271 (b) and/or (c). In the factual and legal bases for Creekwood’s Paragraph IV certification made in connection with Creekwood’s ANDA, Creekwood did not contend that commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Creekwood’s ANDA Products would not infringe one or more claims of the ’189 Patent.

102. Creekwood, via Creekwood's Notice Letter, has indicated that Creekwood's ANDA Products contain either 25 mg or 50 mg of mirabegron in extended-release tablets, as required by one or more claims of the '189 Patent.

103. On information and belief, Creekwood's ANDA Products comprise sustained release hydrogel-forming formulations of mirabegron in a carrier, i.e., contain either 25 mg or 50 mg of mirabegron in extended-release tablets, as required by one or more claims of the '189 Patent.

104. On information and belief, Creekwood followed the Mirabegron Guidance and conducted bioequivalence studies under fasting and fed conditions in comparison with Myrbetriq® Tablets to establish bioequivalence, and Creekwood also followed the Mirabegron Guidance by conducting comparative dissolution testing of Creekwood's ANDA Products against Myrbetriq® Tablets to establish bioequivalence. On information and belief, Creekwood's ANDA Products will have equivalent dissolution properties, and hence equivalent drug release properties, to Myrbetriq® Tablets. Accordingly, because Myrbetriq® Tablets provide a continuous drug release for at least 4 hours after oral administration, Creekwood's ANDA Products likewise also provide a continuous drug release for at least 4 hours after oral administration, as required by the claims of the '189 Patent. Accordingly, because Myrbetriq® Tablets exhibit a difference in a rate of decrease of $C_{max}$ of 10% or more, as compared to an immediate release capsule of mirabegron, on information and belief, Creekwood's ANDA Products likewise reduce the food effect, as required by the claims of the '189 Patent.

105. On information and belief, if Creekwood's ANDA Products are sold, marketed, distributed, and/or imported in the United States, Creekwood knows and intends that physicians, healthcare professionals, and/or patients will prescribe, administer, and/or use Creekwood's ANDA Products according to Creekwood's instructions and/or Creekwood's Label in an infringing manner, and will therefore induce infringement of at least one or more claims of the '189 Patent with the requisite intent under 35 U.S.C. § 271(b).

106. On information and belief, if Creekwood's ANDA Products are sold, marketed, distributed, and/or imported in the United States, Creekwood will sell or offer to sell generic

mirabegron extended-release tablets with provided instructions and/or Creekwood's Label in an infringing manner, wherein Creekwood's ANDA Products are a material part of the claimed invention, wherein Creekwood knows that physicians will prescribe, healthcare providers will administer, and/or patients will use Creekwood's ANDA Products in accordance with Creekwood's provided instructions and/or Creekwood's Label, wherein such use will directly infringe at least one or more claims of the '189 Patent, and wherein generic mirabegron extended-release tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. On information and belief, Creekwood will thus contribute to the infringement of at least one or more claims of the '189 Patent under 35 U.S.C. § 271(c).

107. At least by the filing date of this Complaint, Creekwood will have actual knowledge of the '189 Patent.

108. Unless Creekwood's marketing and sale of Creekwood's ANDA Products prior to the expiration of the '189 Patent and all other relevant activities are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Creekwood's infringement of the '189 Patent. Plaintiffs do not have an adequate remedy at law.

## PRAYER FOR RELIEF

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

A. A judgment that Defendant's submission and maintenance of the Creekwood ANDA constituted an act of infringement of the '780 Patent;

B. A judgment that Defendant's submission and maintenance of the Creekwood ANDA constituted an act of infringement of the '409 Patent;

C. A judgment that Defendant's submission and maintenance of the Creekwood ANDA constituted an act of infringement of the '451 Patent;

D. A judgment that Defendant's submission and maintenance of the Creekwood ANDA constituted an act of infringement of the '189 Patent;

E. A judgment (or a declaration) that Defendant's making, using, offering to sell, or selling in the United States or importing into the United States of Creekwood's ANDA Products will infringe the '780 Patent;

F. A judgment (or a declaration) that Defendant's making, using, offering to sell, or selling in the United States or importing into the United States of Creekwood's ANDA Products will infringe the '409 Patent;

G. A judgment (or a declaration) that Defendant will induce infringement of the '451 Patent;

H. A judgment (or a declaration) that Defendant will induce infringement of the '189 Patent;

I. A judgment (or a declaration) that Defendant will contribute to the infringement of the '451 Patent;

J. A judgment (or a declaration) that Defendant will contribute to the infringement of the '189 Patent;

K. A permanent injunction under 35 U.S.C. §§ 271(e)(4) and/or 283 restraining and enjoining Defendant, its affiliates, subsidiaries, and officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Creekwood ANDA Products until the expiration of the '780 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '780 Patent are or become entitled;

L. A permanent injunction under 35 U.S.C. §§ 271(e)(4) and/or 283 restraining and enjoining Defendant, its affiliates, subsidiaries, officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Creekwood ANDA Products until the expiration of the '409 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '409 Patent are or become entitled;

M. A permanent injunction under 35 U.S.C. §§ 271(e)(4) and/or 283 restraining and enjoining Defendant, its affiliates, subsidiaries, officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Creekwood ANDA Products until the expiration of the '451 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '451 Patent are or become entitled;

N. A permanent injunction under 35 U.S.C. §§ 271(e)(4) and/or 283 restraining and enjoining Defendant, its affiliates, subsidiaries, officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Creekwood ANDA Products until the expiration of the '189 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '189 Patent are or become entitled;

O. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the Creekwood ANDA shall be a date that is not earlier than the expiration date of the '780 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the '780 Patent are or become entitled;

P. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the Creekwood ANDA shall be a date that is not earlier than the expiration date of the ’409 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the ’409 Patent are or become entitled;

Q. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the Creekwood ANDA shall be a date that is not earlier than the expiration date of the ’451 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the ’451 Patent are or become entitled;

R. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the Creekwood ANDA shall be a date that is not earlier than the expiration date of the ’189 Patent, including any extensions and/or periods of exclusivity to which Plaintiffs and/or the ’189 Patent are or become entitled;

S. Damages, including monetary and other relief, to Plaintiffs if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Creekwood ANDA Products prior to the expiration date of the ’780 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs and/or the ’780 Patent are or become entitled;

T. Damages, including monetary and other relief, to Plaintiffs if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Creekwood ANDA Products prior to the expiration date of the ’409 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs and/or the ’409 Patent are or become entitled;

U. Damages, including monetary and other relief, to Plaintiffs if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Creekwood ANDA Products prior to the expiration date of the '451 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs and/or the '451 Patent are or become entitled;

V. Damages, including monetary and other relief, to Plaintiffs if Defendant engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Creekwood ANDA Products prior to the expiration date of the '189 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs and/or the '189 Patent are or become entitled;

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

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

Dated: January 10, 2025

MCCARTER & ENGLISH, LLP

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