**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.,<br><br>Plaintiffs,<br><br>v.<br><br>LUPIN LTD., LUPIN PHARMACEUTICALS, INC., SANDOZ INC., ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED,<br><br>Defendants. | ) | Case No. _____ |

**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:

**THE 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. Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin")**

4. On information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

5. On information and belief, Lupin Ltd. 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. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

7. On information and belief, Lupin Pharmaceuticals, Inc. 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.

**C. Sandoz Inc. ("Sandoz")**

8. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 College Road West, Princeton, NJ 08540.

9. On information and belief, Sandoz 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.

**D. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Zydus")**

10. On information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 N., Pennington, New Jersey 08534.

11. On information and belief, Zydus Pharmaceuticals (USA) Inc. 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.

12. On information and belief, Defendant Zydus Lifesciences Limited is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India.

13. On information and belief, Zydus Lifesciences Limited 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.

## NATURE OF ACTION

14. This is an action for patent infringement of United States Patent No. 11,707,451 ("the '451 Patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to the Abbreviated New Drug Applications ("ANDAs") submitted by the above-named Defendants 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 generic pharmaceutical products.

## JURISDICTION AND VENUE

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

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

17. This Court also has personal jurisdiction over each Defendant because each of its affiliations with the State of Delaware, including in many instances by virtue of its incorporation in the State of Delaware, are so continuous and systematic as to render each Defendant essentially at home in this forum, and in some instances are foreign Defendants that are not subject to jurisdiction in any state's courts of general jurisdiction, making this Court a proper venue for personal jurisdiction.

18. The Court also has personal jurisdiction over each Defendant because, *inter alia*, each has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, each Defendant regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, each Defendant derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware.

19. This Court also has personal jurisdiction over each Defendant because each 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.

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

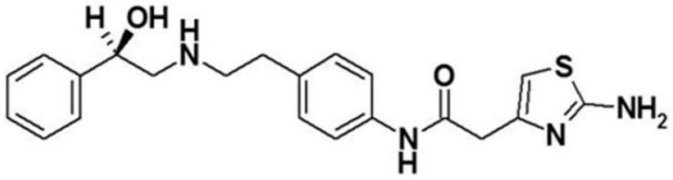
21. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) and/or Fed. R. Civ. P. 4(k)(2).

## MYRBETRIQ® TABLETS

22. APGD holds approved New Drug Application ("NDA") No. 202611 for Myrbetriq® extended-release tablets ("Myrbetriq® Tablets"). The FDA approved NDA No. 202611 on June 28, 2012.

23. Myrbetriq® Tablets contain the active compound mirabegron and are available in two strengths, a 25 mg and 50 mg.

24. 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:




25. Myrbetriq® Tablets comprise sustained release hydrogel formulations of mirabegron 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.

26. The F.D.A. approved Prescribing Information for Myrbetriq® states that Myrbetriq® Tablets are indicated for the treatment of overactive bladder ("OAB"). A true and correct copy of the F.D.A. approved Prescribing Information for Myrbetriq® is attached as **Exhibit A**.

27. The F.D.A. approved Prescribing Information for Myrbetriq® instructs that Myrbetriq® Tablets are for oral use and can be taken by adults with or without food.

28. Myrbetriq® Tablets provide a reduced food effect when compared to the food effect after oral administration of an immediate release mirabegron formulation.

## THE PATENT-IN-SUIT

29. The United States Patent & Trademark Office ("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 B**.

30. 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 mirabegron in a sustained release formulation that provides a continuous drug release for at least 4 hours after oral administration, wherein the sustained release formulation further comprises a carrier, and wherein the reduced food effect is compared to that after oral administration of an immediate release formulation of mirabegron. Additionally, the claimed methods of treating overactive bladder further anticipate and prevent the occurrence of adverse events, including increase in heart rate caused by mirabegron.

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

32. The ’451 Patent will expire no earlier than September 28, 2029.

33. The ’451 Patent’s pediatric exclusivity will extend to March 28, 2030.

34. AICL is the exclusive licensee of the ’451 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.

35. 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.

36. 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.

37. Myrbetriq® Tablets are covered by one or more claims of the ’451 Patent.

38. Plaintiffs will list the ’451 Patent for Myrbetriq® Tablets in FDA’s Orange Book no later than August 24, 2023, which is within the 30 day requirement to list newly-issued patents in the Orange Book. *See* 21 C.F.R. § 314.53(d)(1)-(3).

**MIRABEGRON ANDA APPLICANTS**

39. 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 (“RLD”) for that ANDA product.

40. 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 (“Mirabegron 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 fasted state (i.e. without

food).

41. On information and belief, each mirabegron ANDA filer 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. Accordingly, because Myrbetriq® Tablets exhibit a reduced food effect of mirabegron as compared to an immediate release formulation, on information and belief, each bioequivalent generic mirabegron product will likewise reduce the food effect.

42. The Mirabegron Guidance also requires each mirabegron ANDA filer to conduct comparative dissolution against the Myrbetriq® Tablets. On information and belief, a proposed mirabegron ANDA product will have equivalent dissolution properties, and hence equivalent drug release properties, to Myrbetriq® Tablets.

## CLAIMS FOR RELIEF

### COUNT I: INFRINGEMENT OF THE '451 PATENT BY LUPIN

43. Plaintiffs incorporate by reference and reallege paragraphs 1 through 42 above as though fully restated herein.

44. No later than August 25, 2016, Defendant Lupin submitted to the FDA ANDA No. 209485 for mirabegron extended release tablets, 25 mg and 50 mg ("Lupin ANDA"), a drug product that is a generic version of Myrbetriq® Tablets ("Lupin's ANDA Products") seeking authorization to commercially manufacture, use, import, offer to sell, or sell Lupin's ANDA Products in the United States.

45. Lupin's submission of ANDA No. 209485 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Lupin's ANDA Products, prior to the expiration of the '451 Patent, constitutes infringement of one or more of the claims of the '451

Patent under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin'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).

47. By filing ANDA No. 209485, Lupin has necessarily represented to the FDA that Lupin's ANDA Products have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

48. On information and belief, Lupin's ANDA Products comprise sustained release hydrogel formulations of mirabegron 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.

49. On information and belief, Lupin followed the Mirabegron Guidance and conducted bioequivalence studies under fasting and fed conditions in comparison with Myrbetriq® Tablets to establish bioequivalence. Accordingly, on information and belief, Lupin's ANDA Products will provide a reduced food effect when compared to the food effect after oral administration of an immediate release mirabegron formulation.

50. On September 28, 2022, Lupin received final approval from the FDA for Lupin's ANDA Products. In Lupin's ANDA Approval Letter, the FDA stated that it has "determined [Lupin's ANDA Products] to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), [Myrbetriq® Tablets] … of [Astellas]." (*See* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209485Orig1s000ltr.pdf.)

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

Myrbetriq® Tablets.

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

53. On information and belief, Lupin's Label will indicate that Lupin's ANDA Products are approved for treating overactive bladder.

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

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

56. On information and belief, if Lupin's ANDA Products are sold, marketed, distributed, and/or imported in the United States, Lupin knows and intends that physicians, health care professionals, and/or patients will prescribe, administer, and/or use Lupin's ANDA Products according to Lupin's instructions and/or Lupin'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).

57. On information and belief, if Lupin's ANDA Products are sold, marketed, distributed, and/or imported in the United States, Lupin will sell or offer to sell generic mirabegron extended-release tablets with provided instructions and/or Lupin's Label in an infringing manner, wherein Lupin's ANDA Products are a material part of the claimed invention, wherein Lupin knows that physicians will prescribe, healthcare providers will administer, and/or patients will use Lupin's ANDA Products in accordance with Lupin's provided instructions and/or Lupin'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, Lupin will thus contribute to the infringement of at least one or more claims of the ’451 Patent under 35 U.S.C. § 271(c).

58. On information and belief, Lupin’s actions relating to Lupin’s ANDA No. 209485 were done by and for the benefit of Lupin.

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

60. Unless Lupin’s marketing and sale of Lupin’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 for which, Plaintiffs do not have an adequate remedy at law.

**COUNT II: INFRINGEMENT OF THE ’451 PATENT BY SANDOZ**

61. Plaintiffs incorporate by reference and reallege paragraphs 1 through 60 above as though fully restated herein.

62. No later than September 9, 2016, Defendant Sandoz submitted to the FDA ANDA No. 209441 for mirabegron extended release tablets, 25 mg and 50 mg (“Sandoz ANDA”), a drug product that is a generic version of Myrbetriq® Tablets (“Sandoz’s ANDA Products”) seeking authorization to commercially manufacture, use, import, offer to sell, or sell Sandoz’s ANDA Products in the United States.

63. Sandoz’s submission of ANDA No. 209441 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Sandoz’s ANDA Products, prior to the expiration of the ’451 Patent, constitutes infringement of one or more of the claims of the ’451 Patent under 35 U.S.C. § 271(e)(2)(A).

64. On information and belief, the commercial manufacture, use, offer for sale, sale,

marketing, distribution, and/or importation of Sandoz'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).

65. By filing ANDA No. 209441, Sandoz has necessarily represented to the FDA that Sandoz's ANDA Products have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

66. On information and belief, Sandoz's ANDA Products comprise sustained release hydrogel formulations of mirabegron 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.

67. On information and belief, Sandoz followed the Mirabegron Guidance and conducted bioequivalence studies under fasting and fed conditions in comparison with Myrbetriq® Tablets to establish bioequivalence. Accordingly, on information and belief, Sandoz's ANDA Products will provide a reduced food effect when compared to the food effect after oral administration of an immediate release mirabegron formulation.

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

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

70. On information and belief, Sandoz's Label will indicate that Sandoz's ANDA Products are approved for treating overactive bladder.

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

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

73. On information and belief, if Sandoz's ANDA Products are sold, marketed, distributed, and/or imported in the United States, Sandoz knows and intends that physicians, health care professionals, and/or patients will prescribe, administer, and/or use Sandoz's ANDA Products according to Sandoz's instructions and/or Sandoz'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).

74. On information and belief, if Sandoz's ANDA Products are sold, marketed, distributed, and/or imported in the United States, Sandoz will sell or offer to sell generic mirabegron extended-release tablets with provided instructions and/or Sandoz's Label in an infringing manner, wherein Sandoz's ANDA Products are a material part of the claimed invention, wherein Sandoz knows that physicians will prescribe, healthcare providers will administer, and/or patients will use Sandoz's ANDA Products in accordance with Sandoz's provided instructions and/or Sandoz'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, Sandoz will thus contribute to the infringement of at least one or more claims of the '451 Patent under 35 U.S.C. § 271(c).

75. On information and belief, Sandoz's actions relating to Sandoz's ANDA No. 209441 were done by and for the benefit of Sandoz.

76. At least by the filing date of this Complaint, Sandoz will have actual knowledge of the '451 Patent.

77. Unless Sandoz's marketing and sale of Sandoz'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 for which, Plaintiffs do not have an adequate remedy at law.

**COUNT III: INFRINGEMENT OF THE '451 PATENT BY ZYDUS**

78. Plaintiffs incorporate by reference and reallege paragraphs 1 through 77 above as though fully restated herein.

79. No later than September 6, 2016, Defendant Zydus submitted to the FDA ANDA No. 209488 for mirabegron extended release tablets, 25 mg and 50 mg ("Zydus ANDA"), a drug product that is a generic version of Myrbetriq® Tablets ("Zydus's ANDA Products") seeking authorization to commercially manufacture, use, import, offer to sell, or sell Zydus's ANDA Products in the United States.

80. Zydus's submission of ANDA No. 209488 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Zydus's ANDA Products, prior to the expiration of the '451 Patent, constitutes infringement of one or more of the claims of the '451 Patent under 35 U.S.C. § 271(e)(2)(A).

81. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus'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).

82. By filing ANDA No. 209488, Zydus has necessarily represented to the FDA that Zydus's ANDA Products have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

83. On information and belief, Zydus's ANDA Products comprise sustained release

hydrogel formulations of mirabegron 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.

84. On information and belief, Zydus followed the Mirabegron Guidance and conducted bioequivalence studies under fasting and fed conditions in comparison with Myrbetriq® Tablets to establish bioequivalence. Accordingly, on information and belief, Zydus's ANDA Products will provide a reduced food effect when compared to the food effect after oral administration of an immediate release mirabegron formulation.

85. On April 1, 2019, Zydus received tentative approval from the FDA for Zydus's ANDA Products. In Zydus's ANDA Approval Letter, the FDA stated that it has "determined [Zydus's ANDA Products] to be bioequivalent and, therefore therapeutically equivalent to the reference listed drug (RLD), [Myrbetriq® Tablets] … of [Astellas]." (*See* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/209488Orig1s000TA_ltr.pdf.)

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

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

88. On information and belief, Zydus's Label will indicate that Zydus's ANDA Products are approved for treating overactive bladder.

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

90. On information and belief, Zydus's Label will instruct and encourage healthcare

professionals to practice the claimed methods of the ’451 Patent.

91. On information and belief, if Zydus’s ANDA Products are sold, marketed, distributed, and/or imported in the United States, Zydus knows and intends that physicians, health care professionals, and/or patients will prescribe, administer, and/or use Zydus’s ANDA Products according to Zydus’s instructions and/or Zydus’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).

92. On information and belief, if Zydus’s ANDA Products are sold, marketed, distributed, and/or imported in the United States, Zydus will sell or offer to sell generic mirabegron extended-release tablets with provided instructions and/or Zydus’s Label in an infringing manner, wherein Zydus’s ANDA Products are a material part of the claimed invention, wherein Zydus knows that physicians will prescribe, healthcare providers will administer, and/or patients will use Zydus’s ANDA Products in accordance with Zydus’s provided instructions and/or Zydus’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, Zydus will thus contribute to the infringement of at least one or more claims of the ’451 Patent under 35 U.S.C. § 271(c).

93. On information and belief, Zydus’s actions relating to Zydus’s ANDA No. 209488 were done by and for the benefit of Zydus.

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

95. Unless Zydus’s marketing and sale of Zydus’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 for which, 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 Defendants, and respectfully request the following relief:

A. A judgment that each Defendant's submission and maintenance of its ANDA (i.e., the Lupin ANDA, the Sandoz ANDA, or the Zydus ANDA) constituted an act of infringement of the '451 Patent;

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

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

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

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of each Defendants' 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;

E. Damages, including monetary and other relief, to Plaintiffs if any Defendant

engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of any Proposed ANDA Product, 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;

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 28, 2023

MCCARTER & ENGLISH, LLP

*/s/ Daniel M. Silver*

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