

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

ASTELLAS PHARMA INC., ASTELLAS
IRELAND CO., LTD., and ASTELLAS
PHARMA GLOBAL DEVELOPMENT,
INC.,

Plaintiffs,

v.

C.A. No. 23-819-JFB-CJB

LUPIN LTD., LUPIN
PHARMACEUTICALS, INC., ZYDUS
PHARMACEUTICALS (USA) INC., and
ZYDUS LIFESCIENCES LIMITED,

Defendants.

**ZYDUS PHARMACEUTICALS (USA) INC.’S AND ZYDUS
LIFESCIENCES LIMITED’S ANSWER AND AFFIRMATIVE
DEFENSES TO PLAINTIFFS’ FIRST AMENDED COMPLAINT**

Defendants Zydus Pharmaceuticals (USA) Inc. (“Zydus USA”) and Zydus Lifesciences Limited (“Zydus Lifesciences”) (collectively, “Zydus”), for their Answer and Affirmative Defenses to the First Amended Complaint of Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, “Plaintiffs” or “Astellas”), state as follows:

All averments not expressly admitted are denied.

THE PARTIES

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

1. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 1 and therefore denies them.

2. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore denies them.

3. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore denies them.

B. Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”)

4. The allegations in paragraph 4 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore denies them.

5. The allegations in paragraph 5 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 5 and therefore denies them.

6. The allegations in paragraph 6 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 6 and therefore denies them.

7. The allegations in paragraph 7 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 7 and therefore denies them.

C. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, “Zydus”)

8. Admitted.

9. Zydus admits that Zydus USA files Abbreviated New Drug Applications (“ANDAs”) seeking U.S. Food and Drug Administration (“FDA”) approval to engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of pharmaceutical products and that Zydus USA sells pharmaceutical products, including generic pharmaceutical products, in the United States. Zydus denies all other allegations in paragraph 9.

10. Admitted.

11. Zydus admits that Zydus Lifesciences develops and manufactures pharmaceutical products, including generic pharmaceutical products that are sold in the United States. Zydus denies all other allegations in paragraph 11.

NATURE OF ACTION

12. The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent the allegations in paragraph 12 are directed to Zydus and an answer is required, Zydus admits that Plaintiffs' First Amended Complaint purports to be a civil action alleging infringement of U.S. Patent No. 11,707,451 ("the '451 patent") under Title 35 of the United States Code. Zydus further admits that Zydus USA holds approved ANDA No. 209488 for mirabegron extended-release oral tablets, 25 mg and 50 mg ("Zydus's ANDA Product"). Zydus further admits that Zydus USA is currently offering for sale and selling Zydus's ANDA Product in the United States. To the extent that the allegations in paragraph 12 are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 12.

JURISDICTION AND VENUE

13. The allegations in paragraph 13 state legal conclusions to which no answer is required. To the extent the allegations in paragraph 13 are directed to Zydus and an answer is required, Zydus does not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims under 28 U.S.C. §§ 1331 and 1338(a) against Zydus in this case and solely as they apply to Zydus's ANDA Product. To the extent that the allegations in paragraph 13

are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 13.

14. The allegations in paragraph 14 state legal conclusions to which no answer is required. To the extent the allegations in paragraph 14 are directed to Zydus and an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's ANDA Product. To the extent that the allegations in paragraph 14 are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 14.

15. The allegations in paragraph 15 state legal conclusions to which no answer is required. To the extent the allegations in paragraph 15 are directed to Zydus and an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's ANDA Product. To the extent that the allegations in paragraph 15 are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 15.

16. The allegations in paragraph 16 state legal conclusions to which no answer is required. To the extent the allegations in paragraph 16 are directed to Zydus and an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's ANDA Product. To the extent that the allegations in paragraph 16 are directed to other defendants, Zydus lacks

knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 16.

17. The allegations in paragraph 17 state legal conclusions to which no answer is required. To the extent the allegations in paragraph 17 are directed to Zydus and an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's ANDA Product. To the extent that the allegations in paragraph 17 are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 17.

18. The allegations in paragraph 18 state legal conclusions to which no answer is required. To the extent the allegations in paragraph 18 are directed to Zydus and an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's ANDA Product. To the extent that the allegations in paragraph 18 are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 18.

19. The allegations in paragraph 19 state legal conclusions to which no answer is required. To the extent the allegations in paragraph 19 are directed to Zydus and an answer is required, Zydus does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's ANDA Product. To the extent that the allegations in paragraph 19 are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 19.

MYRBETRIQ[®] TABLETS

20. Zydus admits that FDA's Electronic Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") lists Astellas Pharma Global Development Inc. as the Applicant Holder for New Drug Application ("NDA") No. 202611 for mirabegron extended-release oral tablets, 25 mg and 50 mg, and the Proprietary Name as Myrbetriq. Zydus further admits that the Orange Book lists the approval date for NDA No. 202611 as June 28, 2012 for both the 25 mg and 50 mg mirabegron extended-release oral tablets. Zydus denies all other allegations in paragraph 20.

21. Zydus admits that the Orange Book lists mirabegron as the Active Ingredient for NDA No. 202611 for both the 25 mg and 50 mg strengths of mirabegron extended-release oral tablets. Zydus denies all other allegations in paragraph 21.

22. Zydus admits that the chemical compound with the structure set forth in paragraph 22 has been referred to by the name mirabegron in the prescribing information for Myrbetriq[®] and has the IUPAC designation 2-(2-aminothiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl]acetamide. Zydus lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 22 and therefore denies them.

23. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 23 and therefore denies them.

24. Zydus admits that on information and belief the label for Myrbetriq[®] extended-release oral tablets, 25 mg and 50 mg, available on FDA website at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202611Orig1s017lbl.pdf, includes the statement:

----- **INDICATIONS AND USAGE** -----

MYRBETRIQ is a beta-3 adrenergic agonist indicated for the treatment of:

- Overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency, either alone or in combination with the muscarinic antagonist solifenacin succinate. ([1.1](#))
- Neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older and weighing 35 kg or more. ([1.2](#))

MYRBETRIQ Granules is a beta-3 adrenergic agonist indicated for the treatment of NDO in pediatric patients aged 3 years and older. ([1.2](#))

Zydus further admits that on information and belief that what purports to be a copy of the FDA approved Prescribing Information for Myrbetriq® is attached to the First Amended Complaint as Exhibit A. Zydus denies all other allegations in paragraph 24.

25. Zydus admits that on information and belief the label for Myrbetriq® extended-release oral tablets, 25 mg and 50 mg, available on FDA website at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202611Orig1s017lbl.pdf, includes the following statements:

MYRBETRIQ (mirabegron extended-release tablets), for oral use

* * *

Administration

- **MYRBETRIQ:**
 - Adult patients: Swallow MYRBETRIQ whole with water. Do not chew, divide, or crush. Take with or without food. ([2.7](#))

Zydus denies all other allegations in paragraph 25.

26. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 26 and therefore denies them.

THE PATENT-IN-SUIT

27. The allegations in paragraph 27 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that what purports to be a copy of the '451 patent is attached to Plaintiffs' First Amended Complaint as Exhibit B. Zydus further admits that on its face, Exhibit B to Plaintiffs' First Amended Complaint is titled "Pharmaceutical Composition for Modified Release" and the "Date of Patent" is listed as July 25, 2023. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 27 and therefore denies them.

28. The allegations in paragraph 28 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 28 accurately and completely recite the limitations of the claims of the '451 patent and, therefore, denies the allegations in paragraph 28.

29. The allegations in paragraph 29 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that on its face, the '451 patent lists "Astellas Pharma Inc." as assignee and that the United States Patent and Trademark Office's ("PTO") Patent Assignment Search database, Reel No. 056838, Frame No. 0066, Reel No. 056838, Frame No. 0091, lists "Astellas Pharma Inc." as the assignee of the '451 patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 29 and therefore denies them.

30. Zydus admits only that the Orange Book lists September 28, 2029 as the '451 patent expiration date. Zydus denies all other allegations in paragraph 30.

31. Zydus admits only that the Orange Book lists March 28, 2030 as the '451 patent pediatric expiration date. Zydus denies all other allegations in paragraph 31.

32. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 32 and therefore denies them.

33. Zydus admits that the Orange Book lists Astellas Pharma Global Development Inc. as the Applicant Holder for NDA No. 202611 for mirabegron extended-release oral tablets, 25 mg and 50 mg. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 33 and therefore denies them.

34. Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 34 and therefore denies them.

35. The allegations in paragraph 35 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 35 and therefore denies them.

36. Zydus admits that the '451 patent is currently listed in the Orange Book. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 36 and therefore denies them.

MIRABEGRON ANDA APPLICANTS

37. The allegations in paragraph 37 state legal conclusions to which no answer is required. To the extent the allegations in paragraph 37 are directed to Zydus and an answer is required, Zydus admits that ANDA No. 209488 identifies Myrbetriq® (mirabegron), extended-release oral tablets, 25 mg and 50 mg as the Reference Listed Drug. Zydus further admits that ANDA No. 209488 contains bioequivalence data required by applicable regulations. To the extent that the allegations in paragraph 37 are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 37.

38. Zydus admits that the Federal Register (78 Fed. Reg. 37320 at 30-31 (June 20, 2013)) states that “FDA is announcing new draft product-specific BE recommendations for drug products containing the following active ingredients:” including mirabegron. Zydus further admits that FDA’s Draft Guidance on Mirabegron dated February 2022, available at https://www.accessdata.fda.gov/drugsatfda_docs/psg/PSG_213801.pdf and last accessed on August 15, 2023 (“FDA’s Draft Guidance on Mirabegron”), states that “[t]his guidance, which interprets the Agency’s regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product.” Zydus further admits that FDA’s Draft Guidance on Mirabegron also states:

Active Ingredient: Mirabegron

Dosage Form; Route: For suspension, extended release; oral

Recommended Studies: Two studies

1. Type of study: Fasting
 Design: Single-dose, two-treatment, two-period crossover in vivo
 Strength: 8 mg/mL [Recommended dose: 80 mg (10 mL)]
 Subjects: Males and non-pregnant, non-lactating females, general population
 Additional comments:
 1. Exclude subjects with hypertension and subjects taking muscarinic antagonist drugs for overactive bladder.
 2. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of mirabegron. Alternatively, a parallel study design may be considered.
2. Type of study: Fed
 Design: Single-dose, two-treatment, two-period crossover in vivo
 Strength: 8 mg/mL [Recommended dose: 80 mg (10 mL)]
 Subjects: Males and non-pregnant, non-lactating females, general population
 Additional comments: See comments above.

Zydus denies all other allegations in paragraph 38.

39. To the extent the allegations in paragraph 39 are directed to Zydus, Zydus admits that ANDA No. 209488 contains bioequivalence data required by applicable regulations. To the extent that the allegations in paragraph 39 are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 39.

40. To the extent that the allegations in paragraph 40 are directed to Zydus, Zydus admits that ANDA No. 209488 contains bioequivalence data required by applicable regulations. To the extent that the allegations in paragraph 40 are directed to other defendants, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies them. Zydus denies all other allegations in paragraph 40.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF THE '451 PATENT BY LUPIN

41. Zydus restates and realleges its answers to each of the preceding paragraphs 1-40 as if fully set forth herein.

42. The allegations in paragraph 42 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 42 and therefore denies them.

43. The allegations in paragraph 43 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 43 and therefore denies them.

44. The allegations in paragraph 44 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information

sufficient to form a belief about the truth of the allegations in paragraph 44 and therefore denies them.

45. The allegations in paragraph 45 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 45 and therefore denies them.

46. The allegations in paragraph 46 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 46 and therefore denies them.

47. The allegations in paragraph 47 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 47 and therefore denies them.

48. The allegations in paragraph 48 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 48 and therefore denies them.

49. The allegations in paragraph 49 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 49 and therefore denies them.

50. The allegations in paragraph 50 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 50 and therefore denies them.

51. The allegations in paragraph 51 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 51 and therefore denies them.

52. The allegations in paragraph 52 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 52 and therefore denies them.

53. The allegations in paragraph 53 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 53 and therefore denies them.

54. The allegations in paragraph 54 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 54 and therefore denies them.

55. The allegations in paragraph 55 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information

sufficient to form a belief about the truth of the allegations in paragraph 55 and therefore denies them.

56. The allegations in paragraph 56 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 56 and therefore denies them.

57. The allegations in paragraph 57 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 57 and therefore denies them.

58. The allegations in paragraph 58 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 58 and therefore denies them.

59. The allegations in paragraph 59 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 59 and therefore denies them.

60. The allegations in paragraph 60 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 60 and therefore denies them.

61. The allegations in paragraph 61 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 61 and therefore denies them.

62. The allegations in paragraph 62 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 62 and therefore denies them.

63. The allegations in paragraph 63 are not directed to Zydus. Accordingly, no answer from Zydus is required. To the extent an answer is required, Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 63 and therefore denies them.

COUNT II: INFRINGEMENT OF THE '451 PATENT BY ZYDUS

64. Zydus restates and realleges its answers to each of the preceding paragraphs 1-63 as if fully set forth herein.

65. Zydus admits that no later than September 6, 2016, Zydus USA submitted ANDA No. 209488 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Zydus's ANDA Product. Zydus further admits that ANDA No. 209488 identifies Myrbetriq® (mirabegron), extended-release oral tablets, 25 mg and 50 mg, as the Reference Listed Drug. Zydus denies all other allegations in paragraph 65.

66. Denied.

67. The allegations in paragraph 67 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies the allegations in the first sentence of

paragraph 67. Zydus admits that ANDA No. 209488 identifies Myrbetriq[®] (mirabegron), extended-release oral tablets, 25 mg and 50 mg, as the Reference Listed Drug. Zydus further admits that ANDA No. 209488 contains bioequivalence data required by applicable regulations. Zydus denies all other allegations in paragraph 67.

68. The allegations in paragraph 68 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the allegations in paragraph 68 accurately and completely recite the features of Zydus's ANDA Product, and therefore denies the allegations in paragraph 68.

69. Zydus admits that ANDA No. 209488 contains bioequivalence data required by applicable regulations. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 69 and therefore denies them.

70. Zydus admits that FDA granted tentative approval to ANDA No. 209488 on April 1, 2019. Zydus further admits that FDA stated in the tentative approval letter to Zydus that "[t]he Office of Bioequivalence has determined your Mirabegron Extended-Release Tablets, 25 mg and 50 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Myrbetriq Extended-Release Tablets, 25 mg and 50 mg, of Astellas Pharma Global Development Inc. (Astellas)." Zydus denies all other allegations in paragraph 70.

71. Denied.

72. Denied.

73. Zydus admits that the product labeling for Zydus's ANDA Product complies with applicable law. Zydus further admits that its prescribing information (revised February 2024) states:

----- **INDICATIONS AND USAGE** -----

Mirabegron extended-release tablets are a beta-3 adrenergic agonist indicated for the treatment of:

- Overactive bladder (OAB) in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency. (1.1)

Zydus denies all other allegations in paragraph 73.

74. Zydus admits that the product labeling for Zydus's ANDA Product complies with applicable law. Zydus further admits that its prescribing information (revised February 2024) states:

2.7 Administration Instructions

Mirabegron extended-release tablets

Adult patients: Swallow mirabegron extended-release tablets whole with water. Do not chew, divide, or crush. Take with or without food.

Zydus denies all other allegations in paragraph 74.

75. Denied.

76. Admitted.

77. Zydus admits that it began offering for sale and selling Zydus's ANDA Products on or about April 19, 2024. Zydus denies all other allegations in paragraph 77.

78. Denied.

79. Denied.

80. Zydus admits that Zydus USA is the holder of ANDA No. 209488 and Zydus Lifesciences is the manufacturer for the product identified in ANDA No. 209488. Zydus denies all other allegations in paragraph 80.

81. The allegations in paragraph 81 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the original complaint (D.I. 1) in this action was filed on July 28, 2023 and that it is aware the original complaint is for patent infringement with respect to the '451 patent and that what purports to be a copy of the '451 patent

was attached to the original complaint as Exhibit B. Zydus denies all other allegations in paragraph 81.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

JURY DEMAND

86. Zydus admits only that Plaintiffs have demanded a trial by jury on all issues so triable. Zydus denies all other allegations of paragraph 86.

REQUEST FOR RELIEF

Zydus specifically denies that Plaintiffs are entitled to the general or specific relief requested against Zydus, or to any relief whatsoever, and prays for judgment in favor of Zydus dismissing this action with prejudice, and awarding Zydus its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the First Amended Complaint not otherwise admitted, Zydus avers and asserts the following Affirmative Defenses to Plaintiffs' First Amended Complaint.

FIRST AFFIRMATIVE DEFENSE (Noninfringement of U.S. Patent No. 11,707,451)

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 209488 and/or the manufacture, use, sale, or offer to sell within, and or importation into, the United States of the mirabegron extended-release oral tablets, 25 mg and 50 mg, that are

the subject of ANDA No. 209488 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '451 patent.

**SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,707,451)**

Upon information and belief, the claims of the '451 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**THIRD AFFIRMATIVE DEFENSE
(Lack of Subject Matter Jurisdiction for Claims Under 35 U.S.C. § 271(e)(2))**

Zyodus USA's ANDA No. 209488 has received final approval, and thus, cannot be subject to any claim made under 35 U.S.C. § 271(e)(2).

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs have not suffered any actual injury or damage as a result of any conduct alleged as a basis of this lawsuit.

**FIFTH AFFIRMATIVE DEFENSE
(No Willful Infringement)**

Plaintiffs are not entitled to a finding of willful infringement with a corresponding increase in damages under 35 U.S.C. §284.

**SIXTH AFFIRMATIVE DEFENSE
(Not an Exceptional Case)**

Plaintiffs are not entitled to a finding that this case is exceptional warranting attorneys' fees under 35 U.S.C. §285 to Astellas, or pursuant to the Court's inherent power.

**SEVENTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)**

Plaintiffs' claims for injunctive relief are barred because there exists an adequate remedy at law for Plaintiffs' allegations, and Plaintiffs' claims otherwise fail to meet the requirements for such relief.

**EIGHTH AFFIRMATIVE DEFENSE
(Failure to Mitigate)**

To the extent Plaintiffs suffered any injury, Plaintiffs' claims are barred in whole or in part because Plaintiffs have failed to take reasonable steps to reduce or mitigate the alleged damages.

RESERVATION OF DEFENSES

Zydus hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

Dated: August 6, 2024

YOUNG CONAWAY STARGATT &
TAYLOR, LLP

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 6, 2024, a copy of the foregoing document was served on the counsel listed below in the manner indicated:

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