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. SANDOZ INC., et al. Defendants.	C.A. No. 1:20-01589-JFB-EGT (Consolidated) Honorable Joseph F. Bataillon
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Counterclaimants, v. ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD. and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC., Counterdefendants.	

DEFENDANTS LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC.'S
ANSWER, DEFENSES AND COUNTERCLAIMS

Defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("LPI") (collectively, "Lupin"), through their undersigned counsel, hereby answer the Complaint of Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. ("Plaintiffs") as follows:

To the extent not specifically admitted herein, the allegations of the Complaint are denied.

PARTIES[1]

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

1. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in paragraph 1 and therefore denies those allegations.

2. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in paragraph 2 and therefore denies those allegations.

3. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in paragraph 3 and therefore denies those allegations.

B. Sandoz Inc. ("Sandoz")

4. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 4.

5. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 5.

6. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 6.

7. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 7.

[1] For the Court's convenience, Lupin has incorporated the section titles that appear in the Complaint. Lupin does not necessarily agree with the characterizations of such section titles and does not waive any right to object to those characterizations.

8. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 8.

9. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 9.

C. **Actavis Elizabeth LLC, Actavis LLC and Teva Pharmaceuticals USA, Inc. (collectively, "Actavis")**

10. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 10.

11. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 11.

12. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 12.

13. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 13.

14. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 14.

15. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 15.

16. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 16.

17. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 17.

18. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 18.

19. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 19.

20. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 20.

21. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 21.

D. Apotex Inc. and Apotex Corp. (collectively, "Apotex")

22. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 22.

23. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 23.

24. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 24.

25. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 25.

26. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 26.

27. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 27.

28. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 28.

29. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 29.

30. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 30.

E. Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc. and Aurolife Pharma LLC (collectively, "Aurobindo")

31. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 31.

32. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 32.

33. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 33.

34. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 34.

35. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 35.

36. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 36.

37. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 37.

38. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 38.

39. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 39.

40. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 40.

41. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 41.

F. Sawai Pharmaceutical Co. Ltd. and Sawai USA Inc. (collectively, "Sawai")

42. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 42.

43. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 43.

44. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 44.

45. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 45.

46. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 46.

47. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 47.

48. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 48.

49. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 49.

50. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 50.

51. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 51.

G. Prinston Pharmaceutical Inc., Zhejiang Huahai Pharmaceutical Co. Ltd., Huahai US Inc., and Solco Healthcare US LLC (collectively, "Prinston")

52. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 52.

53. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 53.

54. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 54.

55. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 55.

56. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 56.

57. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 57.

58. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 58.

59. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 59.

60. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 60.

61. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 61.

62. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 62.

H. Windlas Healthcare Pvt. Ltd and Windlas Biotech Ltd. (collectively, "Windlas")

63. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 63.

64. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 64.

65. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 65.

66. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 66.

67. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 67.

68. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 68.

69. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 69.

70. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 70.

71. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 71.

I. Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (d/b/a Zydus Cadila) (collectively, "Zydus")

72. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 72.

73. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 73.

74. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 74.

75. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 75.

76. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 76.

77. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 77.

78. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 78.

79. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 79.

80. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 80.

81. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 81.

J. Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin")

82. Lupin admits that Lupin Ltd. is a corporation organized and existing under the laws of India, having a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. Lupin admits that Lupin Ltd. develops and manufactures generic pharmaceutical products. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 82 of the Complaint.

83. Lupin admits that LPI is a corporation organized and existing under the laws of Delaware and has a place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin admits that LPI distributes generic pharmaceutical drug products in the United States. Lupin denies that LPI is a proper party to Plaintiffs' infringement claim. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 83 of the Complaint.

84. Lupin admits that Lupin Ltd. sent a letter dated August 25, 2016 to Astellas Pharma Inc. and Astellas Pharma Global Development, Inc., entitled "Notice of Paragraph IV Certification Regarding NDA 202611 (Mirabegron) with respect to U.S. Patent Nos. 7,342,117; 7,982,049; 8,835,474; and RE44,872" ("Lupin Ltd.'s Notice Letter"). Lupin admits that Lupin Ltd.'s Notice Letter states that Lupin Ltd. had submitted ANDA No. 209485 to the U.S. Food and Drug Administration ("FDA") seeking approval for a drug product "in the form of extended release tablets, each containing 25 mg or 50 mg mirabegron as the active ingredient" ("Lupin Ltd.'s ANDA Products"). Lupin admits that Myrbetriq® is the reference listed drug for Lupin Ltd.'s ANDA No. 209485. Lupin admits that Lupin Ltd. sought approval to market Lupin Ltd.'s ANDA Products prior to the expiration of U.S. Patent Nos. 7,342,117 ("'117 patent"), 7,982,049 ("'049 patent"), 8,835,474 ("'474 patent"), and RE44,872 ("'872 patent"). Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 84 of the Complaint.

85. Lupin admits that Lupin Ltd.'s Notice Letter states that ANDA No. 209485 includes a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV, with respect to the '117, '049, '474, and '872 patents, indicating that in the opinion of Lupin Ltd. and to the best of its knowledge, the claims of the '117, '049, '474, and '872 patents are invalid, unenforceable and/or will not be infringed by the manufacture, importation, use, or sale of Lupin Ltd.'s ANDA Products. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 85 of the Complaint.

86. Lupin admits that Plaintiffs filed suit against Lupin alleging infringement of the '117, '049, '474, and '872 patents (Astellas Pharma Inc. et al. v. Lupin Ltd. et al., C.A. No. 16¬908 (D. Del.), D.I. 1) ("Plaintiffs' First Complaint"). Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 86 of the Complaint.

87. Lupin admits that in its answer to Plaintiffs' First Complaint, Lupin admitted "that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) solely for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2)," and that Lupin did not contest personal jurisdiction and venue in this Court solely for the purposes of C.A. No. 16-908 (D. Del.). Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 87 of the Complaint.

88. Lupin admits that Plaintiffs and Lupin reached a settlement and all claims between Plaintiffs and Lupin in C.A. No. 16-908 were dismissed. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 88 of the Complaint.

89. Lupin admits that the FDA granted tentative approval to ANDA No. 209485.

90. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 90 of the Complaint.

91. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Lupin Ltd.'s ANDA Products in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 91 of the Complaint.

NATURE OF ACTION

92. Lupin admits that the Complaint filed by Plaintiffs purports to state a civil action for patent infringement arising under the United States patent laws, Title 35, United States Code. Lupin admits that the Complaint alleges infringement of United States Patent No. 10,872,780 ("'780 patent"). Lupin admits that the Complaint purports to concern Lupin's filing of ANDA No. 209485 with the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market generic

pharmaceutical products. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 92 of the Complaint.

JURISDICTION AND VENUE

93. Paragraph 93 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) solely for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2). Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 93 of the Complaint.

94. Paragraph 94 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin further denies that LPI is a proper party to Plaintiffs' infringement claim. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 94 of the Complaint.

95. Paragraph 95 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin further denies that LPI is a proper party to Plaintiffs' infringement claim. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 95 of the Complaint.

96. Paragraph 96 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin further denies that LPI is a proper party to Plaintiffs' infringement claim. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 96 of the Complaint.

97. Paragraph 97 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest personal jurisdiction in this Court for the purposes of this civil action only. Lupin further denies that LPI is a proper party to Plaintiffs' infringement claim. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 97 of the Complaint.

98. Paragraph 98 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin does not contest venue in this Court for the purposes of this civil action only. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 98 of the Complaint.

MYRBETRIQ® TABLETS

99. Lupin admits that, according to the FDA's electronic records, "APGDI" is the holder of New Drug Application ("NDA") No. 202611 for extended release tablets, 25 mg and 50 mg, containing mirabegron as the active ingredient. Lupin admits that the FDA's electronic records list June 28, 2012 as the date of approval for NDA No. 202611. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 99 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 99.

100. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 100 of the Complaint and, therefore, denies each and every allegation in Paragraph 100.

101. Lupin admits that the prescribing information for Myrbetriq®, dated April 2018, states that Myrbetriq® is "indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency[.]" Lupin lacks

sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 101 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 101.

102. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 102 of the Complaint and, therefore, denies each and every allegation in Paragraph 102.

103. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 103 of the Complaint and, therefore, denies each and every allegation in Paragraph 103.

104. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 104 of the Complaint and, therefore, denies each and every allegation in Paragraph 104.

PRIOR MYRBETRIQ® LITIGATION WITH DEFENDANTS

105. This paragraph contains allegations specific to other defendants, which require no response by Lupin. To the extent a response is required, Lupin denies such allegations. Lupin admits that Lupin Ltd. sent Lupin Ltd.'s Notice Letter on August 25, 2016 and that Plaintiffs' First Complaint was filed on October 7, 2016. Lupin admits that Plaintiffs and Lupin reached a settlement and all claims between Plaintiffs and Lupin in C.A. No. 16-908 were dismissed. Lupin admits that Plaintiffs did not assert infringement of the '780 patent in C.A. No. 16-908. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 105 of the Complaint.

106. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of

Lupin Ltd.'s ANDA Products in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 106 of the Complaint.

THE PATENTS-IN-SUIT

107. Paragraph 107 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the face of the '780 patent, the '780 patent, entitled "Pharmaceutical Composition for Modified Release," issued on November 24, 2020. Lupin admits that what purports to be a copy of the '780 patent is attached to the Complaint as Exhibit A. Except as expressly admitted, Lupin denies each and every remaining allegation contained in paragraph 107 of the Complaint.

108. The '780 patent is presently listed in the electronic Orange Book in connection with Myrbetriq®. The electronic Orange Book lists a submission date of "12/11/2020" in connection with the '780 patent. Except as expressly admitted, Lupin denies each and every remaining allegation contained in paragraph 108 of the Complaint.

109. Lupin admits that, according to United States Patent and Trademark Office records, Astellas Pharma Inc. is the assignee of the '780 patent. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 109 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 109.

110. Paragraph 110 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies each and every allegation contained in Paragraph 110 of the Complaint.

111. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 111 of the Complaint and, therefore, denies each and every allegation in Paragraph 111.

112. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 112 of the Complaint and, therefore, denies each and every allegation in Paragraph 112.

113. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 113 of the Complaint and, therefore, denies each and every allegation in Paragraph 113.

114. Paragraph 114 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin denies each and every allegation contained in Paragraph 114 of the Complaint.

MIRABEGRON ANDA FILERS

115. Lupin admits that 78 Fed. Reg. 37230 at 31 (June 20, 2013) relates to bioequivalence recommendations. Lupin admits that the FDA published "Draft Bioequivalence Guidance on Mirabegron" containing nonbinding recommendations. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 115 of the Complaint and, therefore, denies each and every remaining allegation in Paragraph 115.

116. Lupin lacks sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 116 of the Complaint and, therefore, denies each and every allegation in Paragraph 116.

CLAIM FOR RELIEF

COUNT I: INFRINGEMENT OF THE '780 PATENT BY SANDOZ

117. Lupin realleges, and incorporates fully herein, each preceding paragraph 1-116.

118. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 118.

119. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 119.

120. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 120.

121. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 121.

122. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 122.

123. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 123.

124. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 124.

125. This paragraph contains allegations specific to Sandoz, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 125.

COUNT II: INFRINGEMENT OF THE '780 PATENT BY ACTAVIS

126. Lupin realleges, and incorporates fully herein, each preceding paragraph 1-116.

127. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 127.

128. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 128.

129. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 129.

130. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 130.

131. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 131.

132. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 132.

133. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 133.

134. This paragraph contains allegations specific to Actavis, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 134.

COUNT III: INFRINGEMENT OF THE '780 PATENT BY APOTEX

135. Lupin realleges, and incorporates fully herein, each preceding paragraph 1-116.

136. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 136.

137. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 137.

138. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 138.

139. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 139.

140. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 140.

141. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 141.

142. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 142.

143. This paragraph contains allegations specific to Apotex, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 143.

COUNT IV: INFRINGEMENT OF THE '780 PATENT BY AUROBINDO

144. Lupin realleges, and incorporates fully herein, each preceding paragraph 1-116.

145. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 145.

146. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 146.

147. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 147.

148. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 148.

149. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 149.

150. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 150.

151. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 151.

152. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 152.

153. This paragraph contains allegations specific to Aurobindo, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 153.

COUNT V: INFRINGEMENT OF THE '780 PATENT BY SAWAI

154. Lupin realleges, and incorporates fully herein, each preceding paragraph 1-116.

155. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 155.

156. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 156.

157. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 157.

158. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 158.

159. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 159.

160. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 160.

161. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 161.

162. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 162.

163. This paragraph contains allegations specific to Sawai, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 163.

COUNT VI: INFRINGEMENT OF THE '780 PATENT BY PRINSTON

164. Lupin realleges, and incorporates fully herein, each preceding paragraph 1-116.

165. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 165.

166. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 166.

167. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 167.

168. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 168.

169. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 169.

170. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 170.

171. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 171.

172. This paragraph contains allegations specific to Prinston, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 172.

COUNT VII: INFRINGEMENT OF THE '780 PATENT BY WINDLAS

173. Lupin realleges, and incorporates fully herein, each preceding paragraph 1-116.

174. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 174.

175. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 175.

176. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 176.

177. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 177.

178. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 178.

179. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 179.

180. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 180.

181. This paragraph contains allegations specific to Windlas, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 181.

COUNT VIII: INFRINGEMENT OF THE '780 PATENT BY ZYDUS

182. Lupin realleges, and incorporates fully herein, each preceding paragraph 1-116.

183. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 183.

184. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 184.

185. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 185.

186. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 186.

187. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 187.

188. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 188.

189. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 189.

190. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 190.

191. This paragraph contains allegations specific to Zydus, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in paragraph 191.

COUNT IX: INFRINGEMENT OF THE '780 PATENT BY LUPIN

192. Lupin realleges, and incorporates fully herein, each preceding paragraph 1-116.

193. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA seeking approval for a drug product in the form of extended release tablets, each containing 25 mg or 50 mg mirabegron as the active ingredient. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 193 of the Complaint.

194. Lupin denies each and every allegation contained in Paragraph 194 of the Complaint.

195. Lupin denies each and every allegation contained in Paragraph 195 of the Complaint.

196. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Lupin Ltd.'s ANDA Products in the United States. Except as expressly admitted, Lupin denies each and every remaining allegation in Paragraph 196 of the Complaint.

197. Lupin admits that Lupin Ltd. submitted ANDA No. 209485 to the FDA seeking approval for a drug product in the form of extended release tablets, each containing 25 mg or 50 mg mirabegron as the active ingredient. Lupin admits that Myrbetriq® is the reference listed drug for Lupin Ltd.'s ANDA No. 209485. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 197 of the Complaint.

198. Lupin admits that Lupin Ltd. performed bioequivalence studies in connection with ANDA No. 209485. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 198 of the Complaint.

199. Lupin admits that the FDA granted tentative approval to ANDA No. 209485. Except as expressly admitted, Lupin denies each and every remaining allegation contained in Paragraph 199 of the Complaint.

200. Lupin denies each and every allegation contained in Paragraph 200 of the Complaint.

201. Lupin denies each and every allegation contained in Paragraph 201 of the Complaint.

RESPONSE TO PRAYER FOR RELIEF

Lupin denies all allegations not specifically admitted herein, and further denies that Plaintiffs' are entitled to the judgment and relief requested in Paragraphs A-G of the Complaint or to any other relief.

DEFENSES

Without prejudice to the denials set forth in its responses to Paragraphs 1 through 201 of the Complaint, and without undertaking any of the burdens imposed by law on the Plaintiffs, Lupin avers and asserts the following separate defenses to the Complaint. Lupin expressly reserves the right to allege additional defenses as they become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiff has failed to state a claim for which relief can be granted because, inter alia, LPI has not committed an act of infringement as prescribed in 35 U.S.C. § 271(e)(2).

SECOND AFFIRMATIVE DEFENSE
(Lack of Subject Matter Jurisdiction)

This Court lacks subject matter jurisdiction over any and all patent claims asserted against LPI. This Court lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a).

THIRD AFFIRMATIVE DEFENSE
(Non-Infringement)

The manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the '780 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity)

One or more claims of the '780 patent is invalid for failure to comply with one or more of the conditions set forth in Title 35 of the United States Code, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112 and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or the defenses recognized in 35 U.S.C. § 282.

FIFTH AFFIRMATIVE DEFENSE
(Patent Misuse)

The '780 patent is one of several patents that Astellas secured by manipulating the patent process through the use of strategically timed application abandonments and terminal disclaimers. Through this manipulation Astellas has secured several patents, including the '780, '451, '189, and '409 patents, that are duplicative of Astellas' earlier-issued mirabegron patents. Astellas has prosecuted these patents with indifference to their validity and enforceability for the purpose of delaying entry of generic competitors and maintaining an unlawful monopoly through an intricate scheme of serial litigation, tailored litigation settlements, and inequitable patent prosecution. As explained more fully in the counterclaims below, Astellas uses these duplicative patents anticompetitively by filing successive patent infringement actions designed to interfere with competitors in the market of mirabegron. Astellas uses these anticompetitive and

duplicative patents and actions to impermissibly broaden both the physical and temporal scope of Astellas' mirabegron patents. This conduct constitutes patent misuse, at least under *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997).

SIXTH AFFIRMATIVE DEFENSE
(Failure to State a Claim for Exceptional Case)

To the extent the Complaint purports to seek an "exceptional case" determination, the Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Lupin's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

SEVENTH AFFIRMATIVE DEFENSE
(Improper Party)

LPI is not a proper party to Plaintiffs' infringement claims.

EIGHTH AFFIRMATIVE DEFENSE
(Additional Defenses)

Lupin reserves the right to present any additional defenses or counterclaims that discovery may reveal.

DEFENDANT LUPIN LTD.'S AMENDED COUNTERCLAIMS[2]

Defendants/Counterclaimants Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("LPI"), (collectively, "Lupin"), assert against Plaintiffs/Counterdefendants Astellas Pharma Inc.; Astellas Ireland Co., Ltd.; and Astellas Pharma Global Development, Inc. (collectively, "Astellas"), the following counterclaims for violations of Section 2 of the Sherman Antitrust Act, for violations of Delaware state law, and for a declaratory judgment that U.S. Patent Nos. 10,842,780 (the "C'780 patent"); 11,707,451 (the "D'451 patent"); 12,059,409 (the "C'409 patent"); and 12,097,189 (the "D'189 patent"), are invalid and/or not infringed by the manufacture, use, sale, offer for sale, or importation of Lupin's ANDA Products.

INTRODUCTION

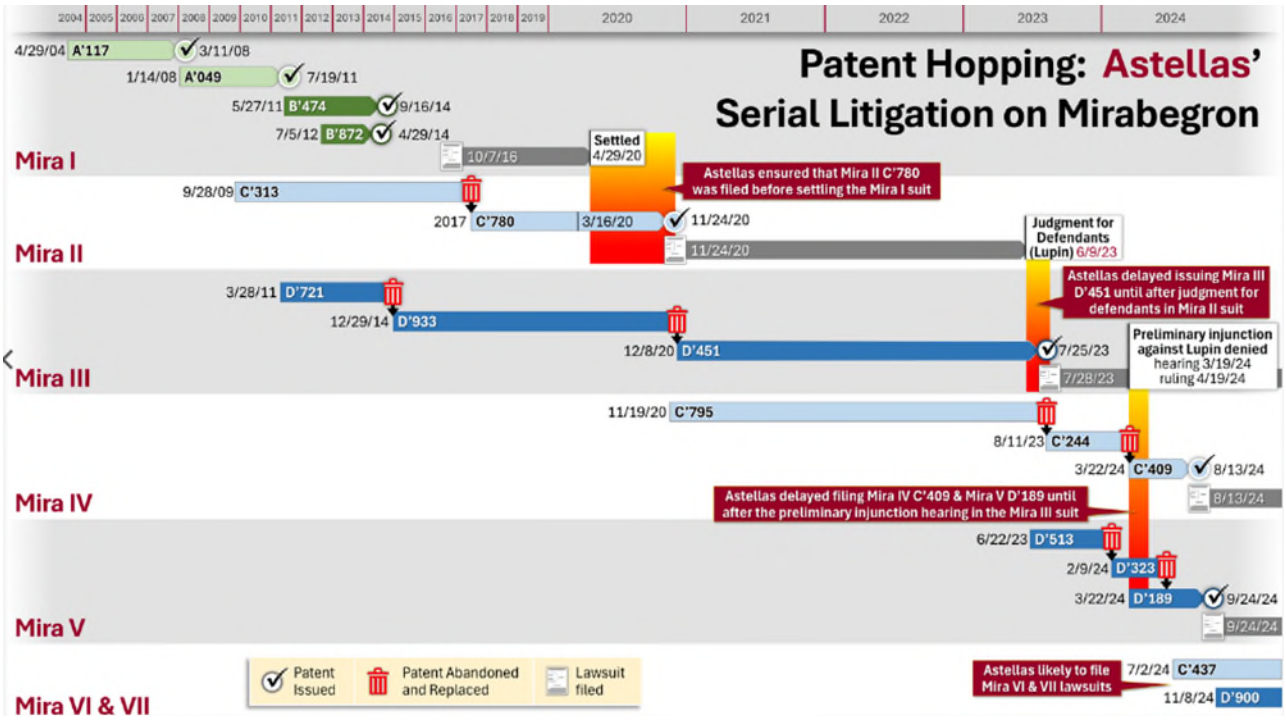
1. This is an action under the Sherman Act and Delaware state law to address and remedy Astellas' anticompetitive, unfair, and illegal scheme to prevent, delay, and raise costs for generic competitors in the market for mirabegron (Myrbetriq®), a prescription drug used to treat overactive bladder (OAB), a condition affecting millions of patients. Because of Astellas' anticompetitive, unfair, and illegal scheme, patients have no choice but to continue paying supracompetitive prices for a drug that should have undergone generic conversion years ago. The only beneficiary of the scheme is Astellas, which through the use of anticompetitive conduct maintained a monopoly that generated more than $1.3 billion in mirabegron revenue in 2023 alone.

[2] *Astellas Pharma Inc. et al v. Sandoz Inc. et al*, No. 1:20-cv-1589 (D. Del.) ("Mira II"), *Astellas Pharma Inc. et al v. Lupin Ltd. et al*, No. 1:23-cv-819 (D. Del.) ("Mira III"), *Astellas Pharma Inc. et al v. Lupin Ltd. et al*, No. 1:24-cv-939 (D. Del.) ("Mira IV"), and *Astellas Pharma Inc. et al v. Lupin Ltd. et al*, No. 1:24-cv-1068 (D. Del.) ("Mira V") have been consolidated. In light of the consolidation of these cases, Lupin's Amended Answer includes its counterclaims for Mira II-V. Lupin has not amended its affirmative defenses in any of Mira II-Mira V and maintains those defenses as originally pled in the Answers in each case.

2. To accomplish this illegal maintenance of its monopoly, Astellas has reimagined and reinvigorated an old trick by engaging in a profound abuse and misuse of the patent system and the United States' courts to perpetuate meritless serial litigation with the sole purpose of leveraging the process to illegally hinder competition. With mirabegron, Astellas has exploited continuation patenting and terminal disclaimers to perpetuate ***eight years of litigation*** across ***five complaints*** featuring ***eight different patents*** (from four different families). All of this for a product for which the original 30-month stay expired in 2019, the original patents expired in 2024, and whose originator has never prevailed against a generic manufacturer in a mirabegron patent litigation. Worse yet, Astellas maintains several mirabegron patent applications "waiting in the wings," and if recent history is any indication, Astellas will use those applications to continue its barrage against generic competitors.

3. A timeline of Astellas' mirabegron-related serial petitioning through patent prosecution manipulation and litigations is shown in the graphic below:[3]

[3] These counterclaims refer to Astellas' mirabegron patent actions as "Mira I" (*Astellas Pharma Inc. et al v. Lupin Ltd. et al*, No. 1:16-cv-908 (D. Del.)), "Mira II" (*Astellas Pharma Inc. et al v. Sandoz Inc. et al*, No. 1:20-cv-1589 (D. Del.)), "Mira III" (*Astellas Pharma Inc. et al v. Lupin Ltd. et al*, No. 1:23-cv-819 (D. Del.)), "Mira IV" (*Astellas Pharma Inc. et al v. Lupin Ltd. et al*, No. 1:24-cv-939 (D. Del.)), and "Mira V" (*Astellas Pharma Inc. et al v. Lupin Ltd. et al*, No. 1:24-cv-1068 (D. Del.)).



4. The patent hopping by Astellas has two parts. First, Astellas assiduously choreographs and times activity before the United States Patent and Trademark Office ("USPTO") to manipulate the issuance of patents while simultaneously protecting Astellas' patents from any meaningful scrutiny. This practice includes 1) timing applications to coincide with dispositive events in ongoing patent litigation, including delaying or speeding up the prosecution of patents, to perpetuate litigation; 2) strategically abandoning applications in favor of continuation applications, evincing both the subjective and objective baselessness of these patents; and 3) assenting to rejections that its patents do not substantively differ from previous patents and terminally disclaiming the new patents to ensure there is no further scrutiny of the patentability by the USPTO, thereby securing the issuance of patents that would otherwise warrant rejection.

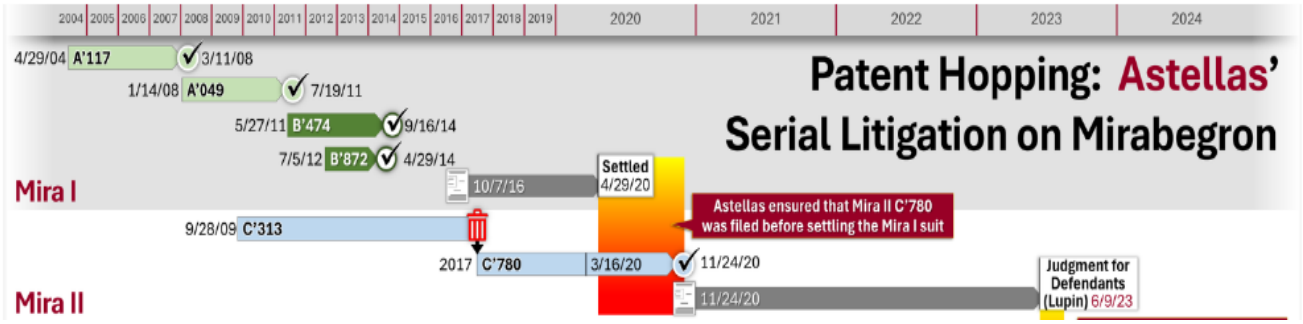
5. Second, Astellas asserts its patents in successive patent infringement actions against its competitors, exploiting the delay that is created from essentially rewinding a litigation

back to its starting block. As soon as a competitor resolves an action with Astellas or promptly after receiving an adverse ruling, Astellas restarts the litigation machine by asserting the patents that it received through the first part of its illegal serial-application (petitioning) scheme. All of these litigations have been a sham as evidenced by Astellas' inability to prevail and willingness to continually abandon its inventions in favor of newly issued patents that disclose no new inventions.

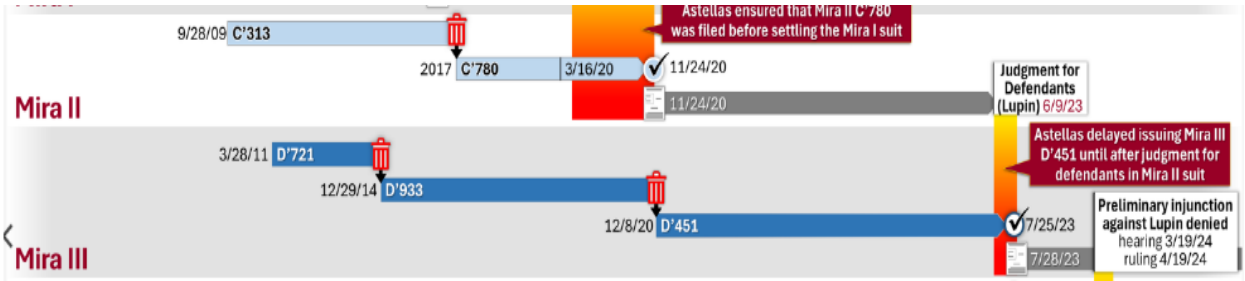
6. These successive actions undermine any resolution reached by the earlier action and force the generic competitors to consider a Hobson's choice: launch a generic mirabegron drug at risk, which exposes the competitor to the continued cost of Astellas' ceaseless litigations, or exit the market, leaving Astellas with a continued monopoly in the market for mirabegron and with the ability to charge supracompetitive prices to the millions of people that use the drug. For the few generic competitors that persist, such as Lupin and Zydus, Astellas' conduct forces the competitors to delay their entry into the market and continues to harass and increase the costs of these competitors even after entry.

7. The weaponization of the patent system through the exploitation of the abandonment and terminal disclaimer process and the commencement of serial litigation by Astellas is illegal. Astellas is not disclosing any invention and is not legitimately securing any right to exclusivity conveyed by the patent laws. And Astellas' conduct is not genuine petitioning of the government that is insulated from antitrust scrutiny by the *Noerr-Pennington* doctrine. Instead, Astellas' conduct is precisely what the antitrust laws proscribe: the use of objectively and subjectively baseless serial petitioning of the United States government without regard for the merits, but instead to leverage the process itself to harm competition.

8. Lupin Ltd. filed an Abbreviated New Drug Application ("ANDA") for mirabegron in 2016. Astellas sued Lupin for patent infringement and after four years, Lupin settled with Astellas, which promptly manipulated the patent process to cause the issuance of a new patent and filed a new action asserting a mirabegron patent. As shown below, Astellas strategically timed the abandonment of a patent application to delay the issuance of any patent until after the settlement in Mira I.



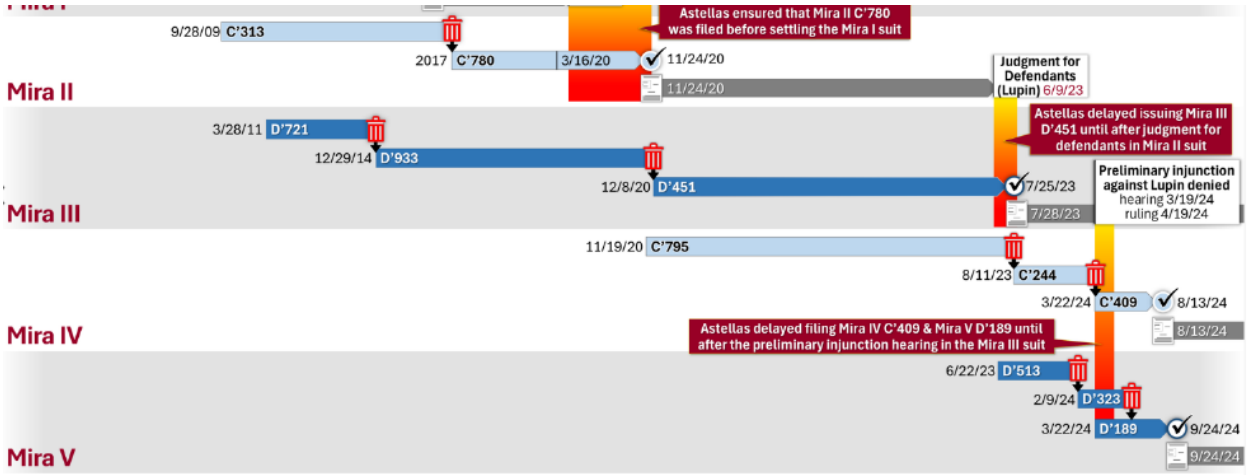
9. Lupin Ltd.'s ANDA was approved during the second action and, after eventually winning the second action at trial and after securing the denial of a preliminary injunction in Astellas' third mirabegron patent action, Lupin launched its generic version of mirabegron. To time its third action, Astellas used its earlier strategy of timing the abandonment of pending patent applications and restarting prosecution with a continuation application in the same patent family.



10. But Astellas was not deterred and continued filing successive actions against Lupin, all of which assert patent infringement for patents covering the same subject matter as the

earlier litigations between Lupin and Astellas. Again, Astellas strategically timed the abandonment of patent applications to control when a patent would issue and when Astellas could file another successive action to interfere with its competition.

11. Lupin continues to litigate the second action and the three duplicative and meritless actions that Astellas filed to interfere with Lupin's commercialization of its generic mirabegron.



12. Astellas has repeated its conduct for almost nine years, during which Astellas has filed, against the same two generic competitors (subtracting those for whom the cost of litigation became too high), five separate patent infringement actions based on eight different patents from four different patent families. In total, Astellas abandoned more than half a dozen applications for mirabegron patents and evaded further substantive examination of several patents by agreeing to terminal disclaimers. Because examiners interpret the terminal disclaimer as assent to their

double-patenting invention, examiners conclude that the new claims are substantively the same as claims that have already been substantively examined and allowed, so further substantive examination of the same claims is pointless. As a result, patents subject to a terminal disclaimer evade a more substantive examination because the patent, though obvious or patentably indistinct, will end on the same day as the earlier-issued patent. This practice prevents the issue of permitting successive terms of patent protection for the same invention, but Astellas manipulates the process to secure different patents that cover the same subject matter and that Astellas can assert in successive litigations.

13. Astellas' anticompetitive tactics prevent, delay, and hinder generic mirabegron manufacturers, such as Lupin, from entering the market for mirabegron. Indeed, at least one currently pending Astellas application appears to be using the same stalling tactic without substantive examination that Astellas used for a previous application, thus foreshadowing yet more vexatious litigation.

14. By delaying the entry of Lupin and other generic competitors, Astellas maintains its monopoly power in the market for mirabegron in the United States and can charge supracompetitive prices for Myrbetriq. Even after a generic competitor launches, Astellas continues to weaponize the patent and litigation processes to harass and harm Astellas' generic competitors in the market for mirabegron.

15. By delaying its competitors' entry and increasing its competitors' costs, Astellas unlawfully maintains monopoly power in the market for mirabegron and inflicts onto millions of patients supracompetitive prices for mirabegron.

16. Astellas' conduct has no procompetitive purpose and violates federal and state law.

PARTIES

17. Lupin Ltd. is a corporation organized and existing under the laws of India, having a registered office at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

18. LPI is a corporation organized and existing under the laws of Delaware and has its principal place of business at 5801 Pelican Bay Boulevard, Suite 500, Naples, Florida 34108. LPI is a wholly-owned subsidiary of Lupin Ltd. LPI distributes generic pharmaceutical drug products in the United States, including the generic mirabegron products that are subject to Lupin Ltd.'s ANDA.[4]

19. On information and belief, and based on Astellas' allegations, Plaintiff/Counterdefendant 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. On information and belief, and based on Astellas' allegations, API was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

20. On information and belief, and based on Astellas' allegations, Plaintiff/Counterdefendant 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.

[4] Because Lupin Ltd. is the ANDA holder, the proper party to Astellas' infringement claim is Lupin Ltd. only, not LPI. However, these counterclaims are asserted on behalf of both Lupin Ltd. and LPI. Astellas' unlawful and anticompetitive conduct detailed in these counterclaims has affected both Lupin Ltd. and LPI by, among other things, delaying Lupin's entry into the market for mirabegron, increasing the cost to market a generic mirabegron product, forcing Lupin to defend successive and meritless patent infringement actions, and damaging Lupin's business opportunities and relations in the market for mirabegron. Consequently, Lupin Ltd. and LPI assert claims under the Sherman Antitrust Act and under Delaware state law.

21. On information and belief, and based on Astellas' allegations, Plaintiff/Counterdefendant Astellas Pharma Global Development, Inc. (APGDI) 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.

JURISDICTION AND VENUE

22. Lupin seeks damages, injunctive relief, and attorney fees based on Astellas' violation of 15 U.S.C. § 2.

23. Lupin seeks damages, injunctive relief, and attorney fees based on violations of Delaware law, including but not limited to 6 Del. Code § 2103.

24. Lupin Ltd. seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

25. The Court has jurisdiction over these Counterclaims pursuant to, at least, 15 U.S.C. § 4; 28 U.S.C. §§ 1331, 1337(a), 1338(a), 1367, 2201, 2202; 35 U.S.C. § 271(e)(2); and 6 Del. Code § 2108(h).

26. Lupin has antitrust standing under 15 U.S.C. §§ 2 and 15. Lupin is a competitor of Astellas in the market for mirabegron in the United States. Astellas' anticompetitive conduct delayed Lupin's entry into the market and, even after Lupin launched at risk, continues to increase Lupin's costs while also creating a dangerous probability of Astellas reobtaining its ill-gotten monopoly. Astellas' anticompetitive conduct allows Astellas to charge supracompetitive prices and further preclude competition in the market for mirabegron. More generally, as a direct result of Astellas' conduct, fewer competitors entered the market and those that entered faced higher costs. This harm is consistent with harm to competition, and Astellas is able to maintain monopoly power and charge supracompetitive prices to patients. These injuries are of the type that the antitrust laws were intended to prevent.

27. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Astellas' choice of forum.

28. Astellas consented to personal jurisdiction by commencing this action in this judicial district.

29. This is an action based on an actual controversy between the parties concerning Astellas' weaponization of the patent and litigation processes in violation of federal and state law.

30. This is an action based on an actual controversy between the parties concerning the invalidity and/or non-infringement of U.S. Patent Nos. 10,842,780 (the "C'780 patent"); 11,707,451 (the "D'451 patent"); 12,059,409 (the "C'409 patent"); and 12,097,189 (the "D'189 patent") and concerning Lupin's right to engage in the commercial manufacture, importation, use, offer for sale, or sale of Lupin's mirabegron extended release tablets (Lupin's ANDA Products) as described in ANDA No. 209485 (Lupin Ltd.'s ANDA).

31. Lupin Ltd. submitted documents to the FDA seeking approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of Lupin's ANDA Products. Astellas has alleged that the submission of Lupin Ltd.'s ANDA and the commercial manufacture, importation, use, offer for sale, or sale of Lupin's ANDA Products infringes, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the C'780, D'451, C'409, and D'189 patents.

32. Astellas has filed in this Court infringement actions to enforce the C'780, D'451, C'409, and D'189 patents against Lupin.

33. On information and belief, and according to Astellas' allegations, API is the assignee of the C'780, D'451, C'409, and D'189 patents.

34. On information and belief, and according to Astellas' allegations, APGDI holds New Drug Application (NDA) No. 202611 for Myrbetriq® (mirabegron extended release tablets).

35. Lupin has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of (literally or under the doctrine of equivalents), any valid and enforceable claim of the C'780, D'451, C'409, and D'189 patents.

36. Astellas' scheme of manipulating the patent process with a web of applications and abandonments, carefully timing the issuance of patents to permit the maximum disruption to competitors, and filing successive patent infringement actions based on the same subject matter violates 15 U.S.C. § 2 and Delaware law.

37. Lupin has further asserted that the C'780, D'451, C'409, and D'189 patents are invalid for failure to satisfy one or more of the provisions of Title 35 of the United States Code, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of a patent, and the defenses recognized in 35 U.S.C. § 282. Astellas listed the C'780, D'451, C'409, and D'189 patents in the electronic Orange Book with respect to Myrbetriq®.

38. In view of the foregoing, a conflict of asserted rights has arisen between Lupin and Astellas with respect to the non-infringement and invalidity of the relevant claims of the C'780, D'451, C'409, and D'189 patents, and as to Lupin's right to obtain FDA approval of its ANDA Products and to engage in the commercial manufacture, importation, use, offer for sale, or sale of its ANDA Products. An actual controversy therefore exists between Astellas and Lupin Ltd.

FACTS COMMON TO ALL COUNTERCLAIMS

I. Legal and Regulatory Framework Common to All Counterclaims

A. Patents

39. A patent confers on the patent-holder the right to prevent others from using an invention for a limited time, typically, for utility patents, twenty years from the filing of the patent application.

40. To receive a patent, a party must submit a patent application, must pay a fee, and must engage in a patent prosecution, a process in which a USPTO examiner reviews an application for a patent.

41. During the prosecution, the examiner determines, among other questions, whether the claims define a useful, novel, and nonobvious invention. The examiner also determines whether the specification contains an adequate written description of and enables the invention.

42. An examiner may issue an Office action, which is written correspondence requiring the applicant to submit a written response to continue the prosecution. An Office action will identify claims that the examiner finds warrant rejection.

43. If an examiner determines that an invention is obvious or anticipated based on an existing patent or invention, the examiner might reject the application. The existence of "prior art" of an invention, which includes previously patented inventions or inventions in public use before the effective filing date of the patent, precludes the issuance of a patent.

44. The examiner may reject one or more claims in a patent, and the applicant enjoys the opportunity to respond to the rejection.

45. If the party's response fails to cure the issues identified by the examiner, the examiner may issue a "Final Rejection," from which the applicant may, for example, appeal the rejection or begin the process again by filing a continuation application.

46. A patent family is two or more patent applications (including resulting patents) that can continuously trace their common disclosures to a single original application (which itself is the earliest member of the family).

47. Child patents or applications are patents and applications based on an earlier-filed patent or application. Child patents or applications often cover a variation of the invention subject to the earlier patent or offer stronger coverage than the parent patent or application.

48. Before the issuance of a patent, the applicant may abandon the application, either by expressly abandoning the application or by failing to timely reply to an Office action. Generally, the applicant has six months to reply to an Office action.

49. Any time before the issuance or abandonment of a patent application, the applicant may file a continuation application, which effectively restarts the patent prosecution. Types of continuation applications include continuation, divisional, and continuation-in-part applications.

50. The continuation application is considered a child application and retains the effective filing date of its parent application.

51. Some companies use continuation patents strategically to secure several patents covering the same or a similar product.

52. A terminal disclaimer is a statement in which the patent applicant disclaims part of the end of a patent's term.

53. Although no person can secure a patent covering the exact same invention as another patent, the USPTO permits the issuance of patents that cover an invention that is patentably-indistinct from another patent granted to the same inventor, subject to a procedural requirement in the form of a terminal disclaimer. In these cases, the patents for each must expire on the same day.

54. Using a terminal disclaimer in this context leads to the granting of more patents of dubious validity because "examiners [] adopt 'softer' examination practices."[5] From the examiner's perspective, the new claims are substantively indistinct from claims that have already been held patentable, so further substantive examination (versus checking formalities) is pointless. Further, from the examiner's perspective, the patent subject to the terminal disclaimer will end at the same time as any earlier patent covering the same invention, eliminating the concern of extending the exclusivity period by permitting a second patent on the same invention. These considerations lead to a less rigorous examination of the merits of the patent subject to the terminal disclaimer.

55. Indeed, this very phenomenon spurred the USPTO to initiate a Notice of Proposed Rulemaking entitled "Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting." As the USPTO explained in the Federal Register notice, the "action is being taken to prevent multiple patents directed to obvious variants of an invention from potentially deterring competition and to promote innovation and competition by allowing a competitor to avoid enforcement of patents tied by one or more terminal disclaimers to another patent having a claim finally held unpatentable or invalid over prior art." The notice goes on to explain "Even with the

[5] Julian Boulanger, *The Examination of Continuation Applications and the Problem of Invalid Patents in the U.S.*, STOCKHOLM SCHOOL OF ECONOMICS, Abstract (2019), available at https://ssrn.com/abstract=3347131.

protections currently provided by a terminal disclaimer, multiple patents tied by terminal disclaimers that are directed to obvious variants of an invention could deter competition due to the prohibitive cost of challenging each patent separately in litigation or administrative proceedings." USPTO subsequently withdrew the proposed rule in light of resource constraints.

56. The child patent issued in these circumstances is often of dubious quality and adds nothing new to promote technical knowledge, but by securing the child patent, the patent holder wields an additional weapon with which to enforce putative intellectual property rights against competitors.

57. By securing these dubious child patents for patentably-indistinct inventions, a patent holder, such as Astellas, can continually file patent infringement actions against competitors, such as Lupin, even after the competitor settles a patent infringement claim for a virtually indistinguishable invention.

58. For mirabegron, Astellas uses this strategy of filing continuation applications and agreeing to terminal disclaimers to secure additional patents of dubious validity. Astellas asserts the patents in successive actions designed to deter competitors from entering the market and to raise the costs of any competitor that ultimately launches a competing product. This is precisely the harm to competition envisioned in the USPTO's Notice of Proposed Rulemaking entitled "Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting."

B. NDA/ANDA

59. Before commercializing a new drug in the United States, the manufacturer of the drug must secure FDA's approval by submitting a New Drug Application (NDA).

60. The NDA discloses data from clinical trials, a list of patents covering the drug, the drug product and/or the approved method of use, and other information that the FDA uses to

determine whether the drug is safe and effective and ultimately whether the drug will receive approval.

61. Before 1984, fewer generic drugs were available to consumers because generic drug manufacturers had to repeat the clinical testing of the branded drug and submit a full application to the FDA.

62. Congress passed the Hatch-Waxman Act to increase competition in the market for drugs and to shorten the process by which generic drugs received FDA approval.[6] According to Pharmaceutical Research and Manufacturers of America, a trade association of which Astellas Pharma is a member, the Hatch-Waxman Act promotes affordability by abbreviating the path for generic manufacturers to bring lower-cost drugs to market.[7]

63. The Hatch-Waxman Act balances "two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."[8]

64. To achieve this balance, the Hatch-Waxman Act offers to generic manufacturers an expedited approval process for generic versions of existing drugs and offers to brand-drug manufacturers additional intellectual property protection, such as additional periods of exclusivity.

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[6] https://www.fda.gov/drugs/cder-conversations/40th-anniversary-generic-drug-approval-pathway#:~:text=The%20Hatch%2DWaxman%20Amendments%E2%80%94named,effectiveness%20of%20the%20generic%20drug; https://www fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda.

[7] https://cdn.aglty.io/phrma/global/blog/import/pdfs/Fact-Sheet_What-is-Hatch-Waxman_June-2018.pdf

[8] Timothy J. Muris, Prepared Statement of the Federal Trade Commission before the Senate Committee on Judiciary (June 17, 2003) (recommending the allowance of only one thirty-month stay for each drug product), *available at* https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-competition-pharmaceutical-industry/030617pharmtestimony.pdf.

65. When filing its NDA, the brand manufacturer discloses to the FDA the patents covering the drug, the drug product and/or the approved method of use, and the FDA lists the patent information in the Orange Book, the FDA's publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

66. The Hatch-Waxman Act permits a generic drug manufacturer to submit an Abbreviated New Drug Application (ANDA), which allows for approval based on bioequivalence with the brand version of the drug.

67. The generic drug manufacturer can establish bioequivalence by showing that the generic drug has similar bioavailability as the branded drug. Establishing bioequivalence does not require a generic manufacturer to repeat the same clinical trials performed by the brand manufacturer.

68. When submitting an ANDA, a generic manufacturer must submit one of four certifications about the status of the applicable patent listed in the Orange Book. The generic manufacturer may certify (1) that no applicable patent is listed in the Orange Book; (2) that the patent listed in the Orange Book has expired; (3) that the generic for which the ANDA is filed will not be approved until the patent expires; or, relevant to these actions, (4) that the listed patent is invalid or not infringed by the generic drug. The fourth option is called a Paragraph IV certification.

69. If the ANDA filer submits a Paragraph IV certification, the brand manufacturer has 45 days to sue the ANDA filer for patent infringement. If the brand manufacturer sues within 45 days, the ANDA is automatically stayed for 30-months, unless the patent expires or is judged to be invalid or not infringed.

70. A brand manufacturer may submit for listing in the Orange Book a patent issued after NDA approval, but, in part because of past abuses by branded drug manufacturers, the listing of an additional patent for the same subject matter confers no second 30-month stay. Likewise, if the patents are listed in the Orange Book after the ANDA is submitted to the FDA, there is no second 30-month stay.

C. Antitrust Laws and Exceptions to the Noerr-Pennington Doctrine

71. The Sherman Act makes unlawful monopolization, that is, the possession of monopoly power in the relevant market and the willful acquisition or maintenance of that power.

72. The Sherman Act makes unlawful attempted monopolization, that is, when predatory or anticompetitive conduct, with a specific intent to monopolize, and a dangerous probability of achieving or maintaining monopoly power as a result of the anticompetitive conduct.

73. Equivalent to the Sherman Act, the Delaware Antitrust Act, 6 Del. Code §§ 2101, et seq., makes unlawful both unlawful monopolization and attempted monopolization.

74. Astellas' manipulation of the patent and litigation processes is both predatory and anticompetitive, and Astellas' manipulation is performed with the specific intent to achieve monopoly power in the market for mirabegron in the United States. Indeed, Astellas has successfully prevented the entry of several potential generic competitors that filed ANDAs but ultimately abandoned their attempts to enter the market because of Astellas' anticompetitive conduct. Moreover, Astellas has already, and continues to, raise the cost for generic rivals through perpetual litigation.

75. The *Noerr-Pennington* doctrine protects from antitrust liability those that legitimately petition the government, including an administrative agency or a court, for redress.

However, *Noerr-Pennington* excepts from this protection sham petitions that are actually nothing more than an attempt to interfere directly with the business relationships of a competitor. There are two exceptions to the *Noerr-Pennington* doctrine, and Astellas' mirabegron campaign fully satisfies both exceptions.

76. First, the *Noerr-Pennington* doctrine does not protect serial petitioning when that series is brought pursuant to a policy of using government process as a means of injuring rivals without regard to the merit of those petitions. To determine a petitioner's intent, courts perform a holistic review, and it is not necessary that each instance within the pattern of serial petitioning independently qualify as objectively and subjectively baseless so long as the court can identify a policy of making such petitions without regard to their merit. This test may include a review of the petitioner's success rate in its legal proceedings, and a high percentage of meritless or objectively baseless proceedings will tend to support a finding that the filings were not brought to redress any actual grievances.

77. Second, the *Noerr-Pennington* doctrine does not apply when an underlying petition is a sham, meaning (1) that no reasonable litigant could realistically expect success on the merits (i.e., the petition is objectively baseless) and (2) that the petition conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process — as opposed to the outcome of that process — as an anticompetitive weapon (i.e., it is subjectively baseless). This sham exception applies to all types of petitioning activity whose process can result in the delay or interference of a competitor's ability to compete. The plausibility of baselessness grows with each new petitioning activity.

78. As explained more fully below, Astellas' intentionally delaying the issuance of new mirabegron patents combined with Astellas repeatedly abandoning pending applications

shows that Astellas is not concerned with the merits of its patent applications. Rather, Astellas merely needs another substantively similar patent to use as a tool to file further litigations against Lupin and Astellas' other competitors.

79. Astellas' serial litigations are filed without regard to merit and for the purpose of using the governmental process, as opposed to the outcome of that process, to harm Lupin and to restrain trade. Even if some of Astellas' earlier litigations were not each objectively baseless, Astellas was unconcerned with the merits. Instead, Astellas used the process itself as an anticompetitive weapon to harm its competitors, including Lupin.

80. Astellas' lawsuits are shams designed to interfere with competitors. Astellas filed successive and duplicative patent infringement actions without regard to the merits of the underlying patent. Astellas has never shown that Lupin infringed one of Astellas' mirabegron patents. In fact, in two of its four pending successive actions, Astellas has received adverse rulings at a trial and on a motion for a preliminary injunction. Further, with each successive action, the plausibility that each action is baseless grows.

II. Facts

A. Astellas and Myrbetriq

81. The FDA approved Myrbetriq, Astellas' branded version of mirabegron, in 2012. Mirabegron is a treatment for overactive bladder, a condition affecting millions of people in the United States alone.

82. Astellas receives more than a billion dollars in annual revenue from sales of Myrbetriq globally.

B. Astellas' Mirabegron Patents

83. Astellas has secured at least eight patents across four patent families for mirabegron. Of these eight patents, four are continuation patents that issued after the launch of Myrbetriq. Each continuation patent issued with a terminal disclaimer that effectively avoided scrutiny by the USPTO.

84. In the process of securing its mirabegron patents, Astellas abandoned at least *seven* applications. These abandonments were an integral part of a strategy to control the rate of patent prosecution and delay the issuance of a patent until Astellas needed the patent to assert in a later patent infringement action designed to interfere with competitors.

i. Family A

85. In its first mirabegron patent family (Family A), Astellas received U.S. Patent 7,342,117 (the A'117 patent), filed October 20, 2002, and issued March 11, 2008, and its child patent, U.S. Patent 7,982,049 (the A'049 patent), filed January 14, 2008, and issued July 19, 2011.

86. The Family A patents cover "α-form or β-form crystal of acetanilide derivative." The A'117 patent claims are directed to either the α-form crystal or β-form crystal of the mirabegron compound. The A'049 patent claims are directed to solid pharmaceutical compositions comprising either the α-form crystal or β-form crystal.

87. The A'049 patent was a continuation patent from the A'117 patent. In other words, Astellas essentially secured two patents on the same subject matter.

88. Likely because Astellas was interested in the merits of the Family A patents (as opposed to using the process against its competitors, like Astellas has done with other patent

families), Astellas abandoned no Family A applications; Astellas worked to secure the prompt issuance of these patents.

89. The year after Astellas received the A'049 patent, Astellas filed its mirabegron NDA.

90. Astellas later asserted both Family A patents in its first mirabegron action against Lupin and other ANDA filers ("Mira I").

91. Astellas has no pending Family A applications.

ii. Family B

92. In the second family (Family B), Astellas received U.S. Patent 8,835,474 (the B'474 patent), filed on May 27, 2011, and issued September 16, 2014, and U.S. Reissue Patent RE44,872 (the B'872 patent), filed July 5, 2012, and issued April 29, 2014.

93. The Family B patents cover a "Remedy for overactive bladder comprising acetic acid anilide derivative as the active ingredient." The B'474 patent claims are directed to a method for treating overactive bladder comprising administering an effective amount of mirabegron as an active ingredient to a patient. The B'872 patent claims are directed to similar subject matter but specify that the subject is not suffering from diabetes.

94. The B'872 patent was a continuation patent from the B'474 patent. In other words, Astellas essentially secured two patents on the same subject matter.

95. Likely because Astellas was interested in the merits of the Family B patents (as opposed to using the process against its competitors, like Astellas has done with other patent families), Astellas abandoned no Family B applications; Astellas worked to secure the prompt issuance of these patents.

96. Astellas later asserted both Family B patents in Mira I.

97. Astellas has no pending Family B applications.

iii. Family C

98. In the third family (Family C), Astellas received U.S. Patent 10,842,780 (the C'780 patent), filed February 14, 2017, and issued November 24, 2020, and U.S. 12,059,409 (the C'409 patent), filed March 22, 2024, and issued August 13, 2024.

99. The Family C patents cover a "Pharmaceutical composition for modified release." The C'780 and C'409 patent claims are directed to pharmaceutical compositions comprising mirabegron in a sustained-release formulation.

100. With Family C, Astellas began its manipulation of the patent process.

101. The first Family C application, the C'313 application, was filed before the issuance of the A'049 patent and before the filing of any Family B application.

102. Unlike the A and B Family applications, Astellas manipulated the prosecution process to delay the issuance of any patent based on the C'313 application. The purpose of the C'313 application (and several other Family C and D applications) was to have a placeholder application until Astellas needed a new patent to assert to interfere with its competitors.

103. The USPTO repeatedly rejected the claims in the C'313 application as obvious over primarily Astellas-owned prior art.

104. The C'313 application was pending for almost eight years—almost six years longer than the average time between the filing of the application and the issuance of a patent.[9] But after Astellas asserted the Family A and B patents in Mira I, Astellas abandoned the C'313 application in favor of a new continuation application, the C'780 application.

[9] https://www.uspto.gov/dashboard/patents/pendency.html.

105. Unless attempting to delay allowance, no rational patent-holder would abandon a pending patent application that would receive priority review and assert broader claims in a new continuation application.

106. The C'780 application further delayed the issuance of any C Family patent; after all, Mira I remained pending, which prevented the entry of any generic competition. Rather than attempt to narrow the claims to move the application toward issuance, the C'780 application recycled claims from the C'313 application.

107. After Astellas settled Mira I, Astellas promptly worked to narrow the claims in the C'780 application and secure the speedy issuance of the C'780 patent.

108. The C'780 patent issued a few months after the Mira I settlement, and on the same day that the patent issued, Astellas filed the first of its successive actions designed to further interfere with the entry of Astellas' competitors ("Mira II").

109. Five days before the C'780 patent issued, Astellas filed a new continuation application in Family C, the C'795 application.

110. Like with the abandoned C'313 application, the C'795 application was rejected as indefinite and obvious over previously-applied art.

111. Astellas avoided amendments that would move the application toward issuance, and the C'795 application languished for almost three years.

112. After the C'795 application was rejected, Astellas waited until near the expiration of the time within which to respond to the rejection and abandoned the C'795 application in favor of a new continuation application in Family C, the C'244 application. Lupin and other competitors had secured a judgment in Mira II two months earlier.

113. However, because Astellas — two weeks after the filing of the C'244 application — filed a new action, Mira III, using the D'451 patent, Astellas worked to continue to delay the issuance of any new Family C patent.

114. To create a delay, Astellas failed to pay the filing fee for the C'244 application. The USPTO informed Astellas that the C'244 application was incomplete because of its failure to pay the fee.

115. Astellas waited until near the end of the time within which to respond to the USPTO, requested an extension, and then filed another application in the C family, the C'409 application. Astellas then abandoned the C'244 application.

116. Astellas' conduct was particularly egregious with respect to the C'244 application because Astellas declined to make any attempt to prosecute the application. Instead, Astellas filed the application without a fee simply to delay by six months the prosecution of any Family C patent application.

117. Astellas had a preliminary injunction hearing in its second successive action ("Mira III") three days before submitting the C'409 application. Knowing that it would soon need a new patent to continue its meritless, serial patent infringement actions, Astellas worked quickly to secure the issuance of a patent from the C'409 application.

118. Unlike the other Family C applications, the C'409 application was filed with a request for prioritized examination, a fee-based mechanism that can significantly shorten the time for examination, and Astellas worked with the examiner to quickly move the application toward issuance. Astellas initiated an interview with the Examiner less than a week after the case was docketed for examination.

119. The claims in the C'409 application were not sufficiently novel to warrant a new patent, but the examiner agreed to the issuance of the C'409 patent conditioned upon Astellas' agreeing to a terminal disclaimer over the C'780 patent. Astellas agreed and filed the terminal disclaimer the same day as the Examiner interview.

120. The chart below shows an example of the incremental differences between the claims in the C'780 patent and the C'409 patent. As the chart shows, the new claim 1 in the C'409 patent is merely an anticipated and obvious iteration of the claim 1 in the C'780 patent. The C'409 patent covers the same product, and Astellas' attempt to narrow the claim confirms that the C'409 patent is indistinct from the C'780 patent.

C'780 (Mira II) – Claim 1	**C'409 (Mira IV) – Claim 1[10]**
A pharmaceutical composition, comprising 10 mg to 200 mg of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, or a pharmaceutically acceptable salt thereof, in a sustained release hydrogel-forming formulation comprising 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.,	A ~~pharmaceutical composition~~ tablet, comprising 10 mg to 200 mg of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, or a pharmaceutically acceptable salt thereof, in a sustained release hydrogel-forming formulation comprising a hydrogel-forming polymer having an average molecular weight of ~~100,000~~ 200,000 to ~~8,000,000~~ 7,000,000 and an additive having a water solubility of at least 0.1 g/mL at 20±5° C.,
wherein the hydrogel-forming polymer is at least one compound selected from the group consisting of polyethylene oxide, hydroxypropyl methylcellulose, hydroxypropyl cellulose, carboxymethyl cellulose sodium, hydroxyethyl cellulose, and a carboxyvinyl polymer,	wherein the hydrogel-forming polymer is ~~at least one compound selected from the group consisting of~~ polyethylene oxide~~, hydroxypropyl methylcellulose, hydroxypropyl cellulose, carboxymethyl cellulose sodium, hydroxyethyl cellulose, and a carboxyvinyl polymer~~,
wherein the additive is at least one selected from the group consisting of polyethylene glycol, polyvinylpyrrolidone, D-mannitol, D-sorbitol, xylitol, lactose, sucrose, anhydrous	wherein the additive is ~~at least one selected from the group consisting of~~ polyethylene glycol~~, polyvinylpyrrolidone, D-mannitol, D-sorbitol, xylitol, lactose, sucrose,~~

[10] Deletions relative to the C'780 claim 1 are shown in red strikethrough font, while additions are shown in green underlined font.

maltose, D-fructose, dextran, glucose, polyoxyethylene hydrogenated castor oil, polyoxyethylene polyoxypropylene glycol, polyoxyethylene sorbitan higher fatty acid ester, sodium chloride, magnesium chloride, citric acid, tartaric acid, glycine, (3-alanine, lysine hydrochloride, and meglumine, and	~~anhydrous maltose, D-fructose, dextran, glucose, polyoxyethylene hydrogenated castor oil, polyoxyethylene polyoxypropylene glycol, polyoxyethylene sorbitan higher fatty acid ester, sodium chloride, magnesium chloride, citric acid, tartaric acid, glycine, (3-alanine, lysine hydrochloride, and meglumine~~, and
wherein a drug dissolution rate from the pharmaceutical composition is 39% or less after 1.5 hours, and at least 75% after 7 hours, as measured in accordance with United States Pharmacopoeia in 900 mL of a USP buffer having a pH of 6.8 at a paddle rotation speed of 200 rpm.	wherein a drug dissolution rate from the ~~pharmaceutical composition~~ **tablet** is 39% or less after 1.5 hours, and at least 75% after 7 hours, as measured in accordance with United States Pharmacopoeia in 900 mL of a USP buffer having a pH of 6.8 at a paddle rotation speed of 200 rpm.

121. The C'409 patent issued in August 2024, and Astellas, having received an adverse ruling on a motion for a preliminary injunction in Mira III, filed another successive patent infringement action the same day ("Mira IV").

122. But consistent with Astellas' earlier conduct, Astellas filed a new Family C continuation application, the C'437 application, shortly before the issuance of the C'409 application.

123. Consistent with Astellas' earlier conduct, the C'437 application has been abandoned.[11]

124. On February 14, 2025, Astellas filed another continuation application in Family C. On information and belief, Astellas is actively continuing its manipulation of the patent process.

[11] Although Astellas has abandoned the C'437 application, the application remains unavailable.

iv. Family D

125. In the fourth family (Family D), Astellas received U.S. 11,707,451 (the D'451 patent), filed December 8, 2020, and issued July 25, 2023, and U.S. 12,097,189 (the D'189 patent), filed March 22, 2024, and issued September 24, 2024.

126. Like the Family C patents, the Family D patents cover a "Pharmaceutical composition for modified release." Specifically, the D'451 and D'189 patent claims are directed to methods for treating overactive bladder with a reduced food effect by orally administering sustained-release tablet formulations of mirabegron.

127. Neither the C nor D Family patents are directed to any new phenomena or discoveries, and neither patent family includes any new compound or indication.

128. Similar to the C'313 application, Astellas filed its first Family D application, the D'721 application before the issuance of the A'049 patent and before the filing of any Family B application.

129. Before filing the D'721 application, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application, including the "Solution to Problem," "Description of Embodiments" and "Examples" sections, as well as the proposed claims.

130. Inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and owed a duty of candor to the USPTO under 37 C.F.R. 1.56.

131. Inventors Kazuhiro Sako, Yuuki Takaishi, and Yutaka Takahashi filed declarations during prosecution of the Family D patents, including the D'721 application, stating

their belief that the contents of the patent applications were truthful to the best of their knowledge under the penalty of perjury.

132. The Family D patents and applications contain a common patent specification that was first included in the D'721 application. All misrepresentations, omissions, and/or falsities contained in the common patent specifications are thus present and affect the validity and/or enforceability of all Family D patents.

133. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the D'721 application and allowed the application to be filed despite awareness that numerous "present inventions" described in the specification were not in possession of the inventors of that time and/or qualified as an "invention" meeting the standards for patentability under 35 U.S.C. 101, 102, 103, and/or 112.

134. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and represented to the USPTO that the inventors were in possession of inventions comprising "[10] a method of reducing an effect of food intake, comprising the step of administering a pharmaceutical composition comprising [mirabegron] or a pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a maximum blood concentration (Cmax) when administered in a fasted state is 400 ng/mL or less" and "[11] a method of reducing an effect of food intake [10] wherein the maximum blood drug concentration (Cmax) when administered in a fasted state is 300 ng/mL or less" despite knowledge that immediate release formulations of mirabegron containing one or more carriers that could be used in sustained release formulation of mirabegron demonstrated

Cmax values less than both 400 ng/mL and 300 ng/mL providing a person of ordinary skill in the art ("POSA") no means for identifying whether a composition would meet the requirements for the reduction of an effect of food intake based on the Cmax values of the compositions.

135. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and represented that the inventors were in possession of inventions comprising:

- [12] a method of reducing an effect of food intake, comprising the step of administering a pharmaceutical composition comprising (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a rate of decrease of a maximum blood drug concentration (Cmax) thereof in comparison with a Cmax of a conventional formulation is 10% or more;
- [13] a method of reducing an effect of food intake, comprising the step of administering a pharmaceutical composition comprising (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a rate of decrease of a maximum blood drug concentration (Cmax) when administered after eating a meal, in comparison with a Cmax when administered in a fasted state, is 10% or more;
- [14] a method of reducing an effect of food intake, comprising the step of administering a pharmaceutical composition comprising (R)-2-(2-aminothiazol-4-

yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a rate of decrease of an area under a blood drug concentration versus time curve (AUC) when administered after eating a meal, in comparison with an AUC when administered in a fasted state, is 10% or more;

- [15] a method of reducing an effect of food intake, comprising the step of administering a pharmaceutical composition comprising (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a dissolution rate of the drug from the composition is less than 85% after 30 minutes from the beginning of a dissolution test;
- [16] the method of reducing an effect of food intake of [15], wherein a dissolution rate is 75% or less after 1.5 hours from the beginning of the dissolution test;
- [17] the method of reducing an effect of food intake of [15], wherein the dissolution rate is 75% or less after 1.5 hours from the beginning the dissolution test, and a dissolution rate is 75% to 100% after 7 hours from the beginning of the dissolution test; and
- [18] the method of reducing an effect of food intake of any one of [10] to [17], wherein the pharmaceutical composition is selected from the group consisting of a sustained release hydrogel-forming formulation, a multi-layered formulation consisting of a drug core and a release-controlling layer which are geometrically

arranged, a gel formulation in which a plurality of gums is combined, an osmotic pump type formulation, a formulation utilizing a swelling polymer, a matrix formulation utilizing a water-soluble polymer, a modified release formulation with a coating membrane, and a matrix formulation utilizing an insoluble polymer.

136. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and represented that the inventors were in possession of invention [12] despite knowledge that the data from clinical studies examining the effect of food intake on sustained release formulations identified in Examples 1A, 1B, and 1C did not include arms wherein an immediate release composition of mirabegron was tested in the same subjects in violation of sound scientific principles and FDA's requirements for comparing between food effect studies, which would demonstrate to a POSA that the inventors were not in possession of any sustained release formulations of mirabegron meeting the description of invention [12].

137. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and represented that the inventors were in possession of inventions [12]-[14] despite knowledge that the data from clinical studies examining the effect of food intake on sustained release formulations identified in Examples 1A, 1B, and 1C, which are identified as embodiments of inventions [12]-[14] included data demonstrating: (1) increases in Cmax values in the fed state over the fasted state; (2) decreases in Cmax values in the fed state over the fasted state less than 10%; (3) increases in AUC values in the fed state over the fasted state; and (4) decreases in Cmax values in the fed state over the fasted state less than 10%, which

would demonstrate to a POSA that the inventors were not in possession of any sustained release formulations of mirabegron meeting the descriptions of in inventions [12]-[14].

138. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and represented that the inventors were in possession of inventions [15]-[17] despite knowledge that many of the trillions of sustained release formulations encompassed by the D'721 patent specification would not meet the dissolution profiles described in inventions [15]-[17], including the formulation of Example 1B, and that an immediate release formulation of mirabegron could meet one or more of the dissolution profiles described in inventions [15]-[17], which would demonstrate to a POSA that the inventors were not in possession of any sustained release formulations of mirabegron meeting the descriptions of in inventions [15]-[17].

139. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and represented that the inventors were in possession of invention [18] despite knowledge of the foregoing regarding inventions [10]-[17] and that the inventors had only conducted food effect experiments on three formulations (Examples 1A, 1B, and 1C) that included a single grade of hydrophilic polymer, polyethylene oxide, and a single grade of water-soluble additive, polyethylene glycol, and had failed to test the remainder of the trillions of sustained release formulations encompassed by the D'721 patent specification, which would demonstrate to a POSA that the inventors were not in possession of any sustained release formulations of mirabegron meeting the descriptions of in inventions [10]-[18].

140. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and represented that the inventors were in possession of inventions comprising:

- [19] a method of inhibiting an increase in heart rate, comprising the step of administering a pharmaceutical composition comprising (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a maximum blood drug concentration (Cmax) when administered in a fasted state is 400 ng/mL or less;
- [20] the method of inhibiting an increase in heart rate of [19], wherein the maximum blood drug concentration (Cmax) when administered in a fasted state is 300 ng/mL or less;
- [21] a method of inhibiting an increase in heart rate, comprising the step of administering a pharmaceutical composition comprising (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a rate of decrease of a maximum blood drug concentration (Cmax) thereof in comparison with a Cmax of a conventional formulation is 10% or more;
- [22] a method of inhibiting an increase in heart rate, comprising the step of administering a pharmaceutical composition comprising (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a

pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a rate of decrease of a maximum blood drug concentration (Cmax) when administered after eating a meal, in comparison with a Cmax when administered in a fasted state, is 10% or more.

- [23] a method of inhibiting an increase in heart rate, comprising the step of administering a pharmaceutical composition comprising (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a rate of decrease of an area under a blood drug concentration versus time curve (AUC) when administered after eating a meal, in comparison with an AUC when administered in a fasted state, is 10% or more;
- [24] a method of inhibiting an increase in heart rate, comprising the step of administering a pharmaceutical composition comprising (R)-2-(2-aminothiazol-4-yl)-4′-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide or a pharmaceutically acceptable salt thereof, and a carrier for a sustained release pharmaceutical composition, wherein a dissolution rate of the drug from the composition is less than 85% after 30 minutes from the beginning of a dissolution test;
- [25] the method of inhibiting an increase in heart rate of [24], a dissolution rate is 75% or less after 1.5 hours from the beginning of the dissolution test;
- [26] the method of inhibiting an increase in heart rate of [24], wherein the dissolution rate is 75% or less after 1.5 hours from the beginning the dissolution

test, and a dissolution rate is 75% to 100% after 7 hours from the beginning of the dissolution test; and

- [27] the method of inhibiting an increase in heart rate of any one of [19] to [26], wherein the pharmaceutical composition is selected from the group consisting of a sustained release hydrogel-forming formulation, a multi-layered formulation consisting of a drug core and a release-controlling layer which are geometrically arranged, a gel formulation in which a plurality of gums is combined, an osmotic pump type formulation, a formulation utilizing a swelling polymer, a matrix formulation utilizing a water-soluble polymer, a modified release formulation with a coating membrane, and a matrix formulation utilizing an insoluble polymer.

141. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and represented that the inventors were in possession of inventions [19]-[27] despite knowledge that the data from clinical studies that demonstrated: (1) sustained release formulations of mirabegron including Examples 1A, 1B, and 1C demonstrated increases in heart rate in both the fasted and fed states; (2) both immediate release and sustained release formulations containing greater than 100 mg of mirabegron demonstrated increases in pulse rate in both the fasted and fed states; and (3) both immediate release and sustained release formulations containing less than 100 mg of mirabegron showed no increase in pulse rate in fasted and fed states, which would demonstrate to a POSA that the inventors were not in possession of any sustained release formulations of mirabegron meeting the descriptions of in inventions [19]-[27].

142. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, and/or attorneys or patent agents of Astellas reviewed the specification of the application and represented that Experimental Example demonstrated that "the reductions of Cmax and AUC caused by food intake could be significantly alleviated by the pharmaceutical composition for modified release of the present invention," despite knowledge that: (1) Example 10 was a comparison of studies conducted in different groups of subjects taking the conventional (immediate release) formulation and those taking sustained release formulations 1A and 1B in violation of sound scientific principles and FDA's guidance for comparing the food effects between different formulations; (2) the data from the clinical studies were taken from two different types of studies, single-dose for the conventional formulation and steady-state for the sustained release formulations 1A and 1B violation of sound scientific principles and FDA's guidance for comparing the food effects between different formulations; (3) the results reported in Example 10 was cherry-picked from all of the results of the two studies and are inaccurate; (4) single-dose results for formulation 1A demonstrated an increase in Cmax in the fed state over the fasted state; and (5) steady state results for both formulations 1A and 1B showed an increase in AUC in the fed state over the fasted state, which would demonstrate to a POSA that the inventors were not in possession of any sustained release formulations of mirabegron meeting the representations in Example 10.

143. Astellas received two Office actions rejecting the claims in the D'721 application, but Astellas avoided amending the claims in a way that moved the application toward allowance. The purpose of the application was not to secure a new patent; the purpose was to delay the issuance of a new patent until the optimal moment for Astellas to use the patent to interfere with its competitors.

144. After receiving a third Office action as to the D'721 application, Astellas filed a new continuation application in Family D, the D'933 application, and abandoned the D'721 application.

145. Astellas slowly prosecuted the D'933 application. Typically, patent applications pend for around 26 months before issuance.[12] But after more than four years of prosecution (and despite Astellas' narrowing the claims several times), the claims were rejected as obvious over prior art.

146. Astellas waited until the end of its time to respond and filed a notice of appeal, which effectively paused the prosecution. After all, Mira I remained pending, and Astellas wanted to delay the issuance of any patent until after the conclusion of its active litigation.

147. Rather than proceed with the appeal, in February 2020—while the parties in Mira I discussed settlement of claims based on the Family A and B patents—Astellas submitted a Request for Continued Examination and responded to the outstanding Office action for the D'933 application. But with its response, Astellas requested an unusual three-month suspension of the prosecution.

148. Again, the purpose of the Family C and D patents was not to protect a novel invention. Astellas was merely manipulating the process to interfere with its competitors' business.

149. The USPTO eventually rejected the claims in the D'933 application because the claims were not enabled but were obvious. Astellas waited until the end of the time to respond to the Office Action, and filed another continuation application Family D, the D'451 application.

[12] https://www.uspto.gov/dashboard/patents/pendency.html.

Two weeks earlier, Astellas had filed Mira II using the C'780 patent. Astellas later abandoned the D'933 application.

150. Before the trial in Mira II, Astellas avoided adding any limitations to the D'451 application that would move the application toward issuance.

151. Unlike its actions in the earlier D family prosecution and after the completion of post-trial briefing in Mira II, Astellas submitted its response to the examiner's initial objections and Astellas, Jason M. Okun, and one or more other attorneys from Venable LLP initiated an interview with the examiner. During the interview, Astellas agreed to implement certain amendments and to file a terminal disclaimer to move the application toward allowance. Shortly thereafter, Astellas submitted its terminal disclaimer over the C'780 patent, and the application was allowed.

152. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, attorneys or patent agents of Astellas, and/or Jason M. Okun and one or more other attorneys submitted the claim amendments discussed with the examiner despite knowledge of the foregoing and that the inventors were not in possession of any sustained release formulations of mirabegron meeting the added limitations and that no such sustained release formulations of mirabegron were described within the common patent specification of the D family.

153. More than a dozen years after Astellas started the D family, it received its first Family D patent when the examiner allowed the issuance of the D'451 patent; and three days later, Astellas asserted the patent in Mira III. Astellas had received an adverse judgment in Mira II less than two months earlier.

154. Repeating its conduct from Family C, Astellas filed a new Family D continuation application, the D'513 application, shortly before the issuance of the D'451 patent.

155. But the D'513 application was merely a placeholder to continue the process. Astellas never intended to prosecute the application and failed to submit the required fees. The USPTO notified Astellas of the missing fee, but as with the C'244 application, Astellas waited until near the expiration of the time within which to respond, without taking any action toward obtaining a patent (not even simply paying the missing fee), and submitted a new Family D application, the D'323 application.

156. With Mira III pending, Astellas needed only another placeholder to continue its manipulation of the patent process. Consequently, Astellas repeated its actions and filed the D'323 application without paying the required fee. The USPTO again notified Astellas of the missing fee to no avail.

157. Instead of paying the fee for the D'323 application, Astellas filed a new Family D application, the D'189 application, a few days after the preliminary injunction hearing in Mira III and on the same day that Astellas filed the C'409 application.

158. Despite failing to pay the fees for the last two Family D patent applications, Astellas submitted the D'189 application with the required fee and with a request for prioritized examination because once again Astellas needed a new patent.

159. On information and belief, one or more of inventors Kazuhiro Sako, Yuuki Takaishi, Yutaka Takahashi, attorneys or patent agents of Astellas, and/or Jason M. Okun and one or more other attorneys submitted the claim amendments to the D'189 application despite knowledge of the foregoing and that the inventors were not in possession of any sustained release formulations of mirabegron meeting the added limitations and that no such sustained

release formulations of mirabegron were described within the common patent specification of the D family.

160. Astellas prosecuted the application for only a few short months before agreeing with the examiner to execute a terminal disclaimer over the D'451 and the C'780 patents. The examiner thought D'189 was substantially the same as another Family D patent, but also substantially the same as a Family C patent, highlighting how insubstantially different all Astellas' later patents are.

161. With the terminal disclaimer, the examiner allowed the D'189 patent to issue. And the same day, Astellas filed its fourth successive action against Lupin ("Mira V").

162. Like the claims in the Family C patents, the claims in the D'189 application were not sufficiently novel to warrant a new patent.

163. The chart below shows an example of the incremental differences between the claims in the D'451 patent and the D'189 patent. Again, the new claim 1 is simply an embodiment within the scope of D'451 claim 1. The D'189 patent covers the same product, and Astellas' attempt to narrow the claim confirms that the D'189 patent is indistinct from the D'451 patent.

D'451 (Mira III) – Claim 1	**D'189 (Mira V) – Claim 1[13]**
A method for treating overactive bladder such that the treating is with a reduced food effect, the method comprising administering orally to a subject in need thereof a tablet comprising 10 mg to 200 mg of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide in a sustained release formulation,	A method for treating overactive bladder such that the treating is with a reduced food effect, the method comprising administering orally to a subject in need thereof a tablet comprising ~~**10 mg to 200 mg**~~ **25 mg** of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide in

[13] Limitations in red strikethrough font has been deleted, while limitations in green underline have been added. The D'189 patent also contains independent claim 16, which recites the same limitations as claim 1, except the dose of mirabegron is 50 mg.

	a sustained release **hydrogel-forming** formulation,
wherein the sustained release formulation further comprises a carrier and provides a continuous drug release for at least 4 hours after oral administration,	wherein the sustained release **hydrogel-forming** formulation further comprises a carrier and provides a continuous drug release for at least 4 hours after oral administration,
wherein the sustained release formulation is any one selected from the group consisting of a sustained release hydrogel-forming formulation, a multi-layered formulation consisting of a drug core and a release-controlling layer which are geometrically arranged, a gel formulation in which a plurality of gums are combined, an osmotic pump type formulation a formulation utilizing a swelling polymer, a matrix formulation utilizing a water-soluble polymer, a modified release formulation with a coating membrane, and a matrix formulation utilizing an insoluble polymer, and	~~**wherein the sustained release formulation is any one selected from the group consisting of a sustained release hydrogel-forming formulation, a multi-layered formulation consisting of a drug core and a release-controlling layer which are geometrically arranged, a gel formulation in which a plurality of gums are combined, an osmotic pump type formulation a formulation utilizing a swelling polymer, a matrix formulation utilizing a water-soluble polymer, a modified release formulation with a coating membrane, and a matrix formulation utilizing an insoluble polymer, and**~~
wherein the reduced food effect is compared to that after oral administration of an immediate release formulation comprising (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide.	wherein the reduced food effect is compared to that after oral administration of an immediate release formulation comprising (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide~~.~~**, and is a difference in a rate of decrease of C_{max} of 10% or more, and**
	wherein the immediate release formulation is a capsule.

164. Consistent with Astellas' earlier conduct, Astellas filed a new Family D continuation application, the D'900 application, shortly before the issuance of the D'189 patent.

165. The D'900 application remains pending, and consistent with Astellas' earlier conduct, Astellas will almost certainly delay the prosecution of the application until Astellas needs a new patent to interfere with its competitors for mirabegron.

C. Astellas' Successive Litigations against Lupin and other Competitors

i. Mira I: Astellas Pharma Inc. et al v. Lupin Ltd. et al, No. 1:16-cv-908 (D. Del.)

166. In June 2016, Lupin Ltd. and other generic manufacturers filed ANDAs on both the 25mg and 50mg versions of mirabegron and submitted Paragraph IV certifications against Astellas' Family A and B patents (the only mirabegron patents that Astellas had at that time).

167. In October 2016, Astellas sued Lupin and the other ANDA filers and asserted the A'117, A'049, B'474, and B'872 patents.

168. At the time of filing in Mira I, no C or D Family patent had issued, but Astellas had filed applications, which were later abandoned, in both the C and D Families. These abandonments are evidence of the baselessness of the petitioning before the USPTO and of the eventual litigation filed regarding these patents. Astellas filed the first C and D Family applications before the approval of Myrbetriq but intentionally delayed the prosecution of each to cause new patents to issue after the A and B Family patents were asserted in a later action. Astellas' objective was not to secure meritorious patents covering a novel invention. Astellas maintained the C and D Family applications as tools to use to extend its monopoly in the market for mirabegron.

169. In April 2020, Astellas settled the action and granted a license to Lupin.

ii. Mira II: Astellas Pharma Inc. et al v. Sandoz Inc. et al, No. 1:20-cv-1589 (D. Del.)

170. Before and during the prosecution of Mira I, Astellas delayed the prosecution of, and ultimately abandoned, the C'313 application.

171. The USPTO repeatedly rejected the claims in the C'313 application as obvious over primarily Astellas-owned prior art.

172. In 2017, Astellas filed a continuation application based on the C'313 application and abandoned the C'313 application.

173. The continuation application, which was ultimately granted as U.S. Patent 10,842,780 (the C'780 patent), initially included earlier-attempted, broader claims from the C'313 application, rather than the narrower claims achieved during the C'313 prosecution.

174. By reverting to earlier, broader claims, Astellas strategically delayed the issuance of a patent.

175. As shown by Astellas' actions, Astellas' objective was not to quickly obtain a patent to protect a new invention. Rather, Astellas needed to choreograph the issuance of a patent to assert in a later litigation against Lupin and other generic manufacturers.

176. Because the continuation application that later issued as the C'780 patent was pending at the time of the Mira I settlement, the settlement applied to neither the application nor the later-issued C'780 patent.

177. In June 2020, shortly after signing the settlement in Mira I, Astellas narrowed the claims in its pending continuation application.

178. The examiner allowed the narrower claims, and the C'780 patent issued on November 24, 2020.

179. Five days before the issuance of the C'780 patent, Astellas filed another patent application in the C family, U.S. Divisional Application 16/952,795 (the C'795 application), which was abandoned on August 21, 2023. Like other abandonments, this abandonment is evidence of Astellas' pattern of using litigation to interfere with Lupin's business and hinder competition.

180. Astellas used the C'795 application as a placeholder until it needed another patent to assert in its successive litigations.

181. On the same day that the C'780 patent issued, Astellas filed Mira II and asserted the C'780 patent against generic manufacturers, including Lupin and other generic manufacturers who settled with Astellas in Mira I.

182. Faced with the new litigation, Lupin's and the other generic manufacturers' entry was delayed despite the settlement in Mira I.

183. During the pendency of Mira II, Astellas entered into settlement agreements with a number of ANDA applicants for sustained release mirabegron formulations, which contained terms that eliminated or delayed potential entry dates for the ANDA products based solely on the issuance and listing of new patents in the Orange Book for Myrbetriq regardless of whether those patents were properly obtained, valid, and/or enforceable.

184. After a bench trial, this court entered a judgment declaring patent C'780 invalid, and Astellas appealed.

185. On appeal, the Federal Circuit reversed because the district court decided the case using a theory not argued or developed by the parties.

186. During the pendency of the appeal, Lupin and Zydus launched their mirabegron generics at risk.

iii. Mira III: Astellas Pharma Inc. et al v. Lupin Ltd. et al, No. 1:23-cv-819 (D. Del.)

187. Between 2011 and 2015, Astellas prosecuted the first D family application, D'721.

188. The USPTO twice rejected the D'721 application's claims as anticipated or obvious over Astellas-owned prior art.

189. Astellas intentionally avoided amendments that might move the application toward allowance.

190. Again, Astellas' conduct shows that the merits of the patent were unimportant; Astellas needed only to time the issuance of the patent until Astellas could assert the patent in a new litigation and further interfere with Lupin and Astellas' other generic competitors.

191. In December 2014, Astellas filed another D family application, U.S. Divisional Application 14/584,933 (the D'933 application), which was filed December 29, 2014, and abandoned on February 2, 2021.

192. After filing the D'933 application, Astellas abandoned the D'721 application.

193. Astellas prosecuted the D'933 application until January 2019, when the examiner found that the claims were obvious over the prior art and entered a final rejection.

194. Near the end of the six-month time to respond to the rejection, Astellas filed a notice of appeal, which effectively suspended the prosecution of the D'933 application.

195. Because Mira I was pending at this time and Astellas was prosecuting a patent in the C Family, Astellas needed to delay the issuance of any D Family patent. Delaying the patent allowed Astellas to assert the patent in a later litigation and further Astellas' tactic of filing successive actions to prevent, delay, and hinder the entry of any generic competition.

196. In February 2020, while the parties discussed settlement in Mira I, Astellas submitted a request for continued examination and a response to an outstanding USPTO action for the D'933 application.

197. Astellas canceled all pending claims, except claims directed to a tablet.

198. Also, Astellas requested a three-month suspension of prosecution on the D'933 application.

199. After the conclusion of Mira I, the examiner again rejected the D'933 application's claims as obvious and not enabled.

200. Astellas waited almost the maximum amount of time before filing another child application in the D family and later abandoned the D'933 application.

201. The child application, which was filed December 8, 2020, eventually resulted in the issuance of U.S. Patent 11,707,451 (the D'451 patent).

202. In April 2023, shortly after the conclusion of post-trial briefing in Mira II, Astellas worked to expedite the issuance of patent D'451 and agreed with the examiner to amend the independent claim.

203. Because of the adverse ruling in Mira II, Astellas worked to quickly issue and assert in an action a new patent based on similar subject matter. Astellas' tactic did not require a substantively different or meritorious patent; Astellas needed only a new patent from which it could begin a new litigation and further prevent, delay, and hinder generic entry.

204. The D'451 patent issued on July 25, 2023, and Astellas filed Mira III within three days.

205. Like with the C'780 patent, shortly before the issuance of the D'451 patent, Astellas filed another patent application in the D family, U.S. Application 18,339,513 (the D'513 application).

206. Again, Astellas used this application as a placeholder only, until the time was ripe to file a new suit to further frustrate potential generic entrants in the market for mirabegron.

207. Mira III remains pending, but this Court, adopting the magistrate judge's report and recommendation, denied Astellas' motion to preliminarily enjoin Lupin and others from selling their mirabegron generics.

208. Specifically, the order adopting the magistrate judge's report and recommendation states "the [D]'451 patent is not likely to withstand an invalidity challenge on the ground that the claims are indefinite because the 'reduced food effect' limitation likely fails to provide objective boundaries in light of the specification and prosecution history."

209. On April 19, 2024, when the magistrate judge issued the report and recommended the denial of Astellas' motion for a preliminary injunction, Lupin and Zydus launched their generic mirabegron products at risk.

210. The same day, Astellas moved for a temporary restraining order ("TRO") to prevent Lupin and Zydus from marketing and selling their generic mirabegron.

211. Likely anticipating that the motion for a TRO would fail in Mira III, on April 22, 2024, Astellas filed a similar motion for a TRO in the appeal in Mira II, which was pending at the time. The appeals court granted the temporary restraining order without analysis and before Lupin or Zydus could respond.

212. On April 24, 2024, Judge Bataillon adopted the report and recommendation in Mira III, denied the motion for a preliminary injunction, and denied the motion for a TRO.

213. On April 25, 2024, Lupin and Zydus responded to the motion for a TRO in the Mira II appeal.

214. On May 9, 2024, after reviewing Lupin's and Zydus' response, the appeals court lifted the TRO and refused to issue an injunction pending the Mira II appeal.

215. Astellas' duplicative TROs were more attempts in its serial litigations to weaponize the litigation process to interfere with Lupin's and Zydus' marketing and selling a competing mirabegron product. Astellas was unconcerned with the ultimate merits of the TROs

(in fact, Astellas seemingly anticipated that the TROs would ultimately fail). Astellas merely used another procedural tool to the detriment of its competitors.

iv. Mira IV: Astellas Pharma Inc. et al v. Lupin Ltd. et al, No. 1:24-cv-939 (D. Del.)

216. Five days before the issuance of the C'780 patent (the patent at issue in Mira II), Astellas submitted the C'795 application, which like many of Astellas' mirabegron patent applications was rejected as indefinite and obvious over previously-applied art.

217. Astellas waited until near the expiration of the time within which to respond to the rejection and filed another continuation patent application, U.S. Continuation Application 18/448,244 (the C'244 application). Astellas later abandoned the C'795 application.

218. Astellas failed to pay the required fee for the C'244 application.

219. The USPTO informed Astellas that the C'244 application was incomplete because of the failure to pay the fee.

220. Astellas again waited until near the end of the time within which to respond, requested an extension, and filed another application in the C family.

221. The newly-filed application, which was filed March 22, 2024, would later issue as U.S. Patent 12,059,409 (the C'409 Patent).

222. After the magistrate judge recommended denying Astellas' request for a preliminary injunction in Mira III, Astellas filed a request for prioritized examination of its most recent C family patent application.

223. Regardless of any adverse decision or the merits of the underlying patent, Astellas intended to prompt the issuance of a new patent that it could assert to further prevent, delay, and hinder Lupin and other generic competitors.

224. The C'409 patent issued on August 13, 2024, and Astellas filed Mira IV on the same day.

v. Mira V: Astellas Pharma Inc. et al v. Lupin Ltd. et al, No. 1:24-cv-1068 (D. Del.)

225. In coordination with its prosecution of the application leading to the issuance of the C'409 patent and with the filing of Mira IV, Astellas strategically timed the issuance of a new D family patent, U.S. Patent 12,097,189 (the D'189 Patent).

226. When Astellas submitted the D'513 application, the application that Astellas filed shortly before the issuance of the D'451 patent at issue in Mira III, Astellas failed to pay the required fee.

227. Astellas' actions show that Astellas had no interest in securing protection for a novel invention. Rather, Astellas needed to strategically delay the issuance of a patent that Astellas could later assert in a litigation designed to frustrate generic competition.

228. The USPTO notified Astellas of the missing fee, and shortly before the expiration of the time within which to respond, Astellas submitted another D family patent application, U.S. Application 18/437,323 (the D'323 application), which was filed February 9, 2024, and abandoned on December 12, 2024.

229. Astellas again failed to pay the required fee for the D'323 application.

230. Three days after the preliminary injunction hearing in Mira III, Astellas filed a new D family patent application, which resulted in the issuance of the D'189 Patent.

231. To expedite the issuance of the D'189 patent, Astellas submitted a request for prioritized examination, substituted narrower versions of the claims from the D'451 patent, and agreed to a terminal disclaimer over both patent C'780 and patent D'451.

232. The D'189 patent issued on September 4, 2024, and Astellas filed Mira V on the same day.

233. Unlike with Mira II and Mira III, Astellas filed Mira IV and Mira V within two months. Lupin and Zydus launched at risk after the judgment against Astellas in Mira II, and Astellas lost the preliminary injunction motion in Mira III. To continue interfering with the operations of Lupin and Zydus and to attempt to increase their costs and drive them from the market, Astellas filed two successive actions almost simultaneously.

234. Mira IV and Mira V are meritless. Astellas' intent in filing the actions concurrently is to continue to prevent the entry of generic competition and to raise the costs on Lupin and Zydus. As long as the actions help Astellas secure monopoly power in the market for mirabegron, Astellas is indifferent as to the merits of the underlying actions.

D. Active Litigations and At-Issue Patents

235. Astellas strategically times the issuance of its patents to delay the entry of, and increase the costs of, generic competitors and to maintain monopoly power in the mirabegron market.

236. For example, Astellas has, and will continue to, use later-issued patents to begin new litigation after receiving adverse rulings in pending litigations.

237. Each successive patent issuance and litigation delays or hinders the entry of generic competitors in the market for mirabegron.

238. Lupin and other generic competitors potentially face severe consequences, including treble damages, for launching a product that is found to infringe a patent, even if Lupin or another generic received a license to use an invention covered by a virtually indistinguishable patent.

239. The threat of treble damages and the significant expenditure of time and resources to litigate the successive actions delay and often prevent the entry of generic competitors, regardless of the merits of the patent at issue.

240. For example, Astellas' anticompetitive conduct delayed Lupin's entry into the market for mirabegron until April 2024, after the trial in Mira II. Lupin lost any sales, profits, and business opportunities that Lupin would have enjoyed absent Astellas' successive actions.

241. Defending successive actions squanders the resources of the judiciary and the generic manufacturers, including Lupin. Each concurrent action increases Lupin's and other generic manufacturers' costs and attempts to drive from the market the few competitors that dared to launch despite Astellas' seemingly endless stream of patent applications and infringement actions. Further, each action accuses Lupin of infringing Astellas' intellectual property, and those allegations harm Lupin's prospective business relations.

242. Even when Astellas' patents were plainly obvious or indistinct from an earlier patent, Lupin and other generic manufacturers were forced to defend successive actions despite earlier resolution of the underlying issues.

243. The litigation process itself causes harm to the generic manufacturer forced to defend successive actions.

244. Astellas presently litigates Mira II-V against Lupin and other generic manufacturers.

245. Because Mira III-V are duplicative of Mira II and are based on patents covering the same subject matter as Mira II, the actions have been consolidated.

246. These actions are objectively baseless because Astellas cannot realistically expect success on the merits of the actions and is instead using its serial litigations to weaponize the

patent and litigation processes to harm its competitors, including Lupin. The merits of the underlying actions are irrelevant for Astellas' purpose of interfering with its competitors.

247. These actions are shams masking Astellas' intent to use the litigation process to prevent, delay, hinder, and harass generic manufacturers for mirabegron.

248. By interfering with the entry of generic competitors, Astellas maintains monopoly power in the market for mirabegron and can charge higher prices.

249. The patents at issue in Mira II, Mira III, Mira IV, and Mira V cover the same subject matter.

250. The patents are obvious based on patents asserted in Mira I and based on Astellas' prior art.

251. Many of the claims in Astellas' mirabegron patents cover similar subject matter. The C'409 patent and the D'189 patent include claims that copy generously from earlier claims from patents in the same family.

252. Astellas has two more pending patent applications, one C family application and one D family application.

253. One month before the issuance of the C'409 patent, Astellas filed U.S. Continuation Application 18/761,437 (the C'437 application, filed July 2, 2024).

254. Shortly before abandoning the D'323 application, Astellas filed U.S. Continuation Application 18/940,900 (the D'900 application, filed November 8, 2024).

255. Last month, Astellas filed — yet another — patent application in Family C, the C'451 application.

256. Astellas maintains the C'451 application and the D'900 application as placeholders to strategically time the issuance of new patents, which Astellas can assert in future duplicative litigation.

257. Maintaining the C'451 and D'900 applications will allow Astellas to continue its strategy of using the litigation process to interfere with generic competition, regardless of the outcome of Mira II, Mira III, Mira IV, and Mira V.

MARKET POWER

258. The relevant antitrust market is mirabegron and its generic equivalents (the "mirabegron market").

259. At all relevant times prior to generic competition, Astellas maintained market power over the mirabegron market. Astellas had the power and ability to maintain the prices for mirabegron at supracompetitive levels, and increases in price did not result in a significant loss of sales. Indeed, announcing its financial results for the 2023 fiscal year, Astellas noted that "[s]ales of [Myrbetriq are] expected to decrease from the effect of generic brands."[14]

260. Astellas continues to exercise market power through its patent hopping scheme to artificially and illegally raise the costs of its only rivals in the mirabegron market, generic manufacturers. Through this conduct, Astellas continues to maintain Myrbetriq prices at supracompetitive levels.

261. Astellas' power to profitably raise its Myrbetriq prices above the competitive level results from Astellas' unlawful and anticompetitive manipulation of the patent and litigation processes, including Astellas' strategically timing the abandonment of patent applications to delay the issuance of patents, Astellas' serially agreeing to terminal disclaimers to

[14] https://www.astellas.com/en/system/files/0e87eb8225/4q2023_en.pdf.

secure the issuance of otherwise obvious patents, and Astellas' asserting its patents in successive actions based on the alleged infringement of the same subject matter as earlier infringement actions.

262. Because state laws prohibit pharmacists from dispensing pharmaceutical products, such as mirabegron, unless a patient has a prescription from a doctor, the patient's doctor selects the product that a patient (or the patient's insurer) will buy.

263. The existence of other treatments for OAB did not adequately constrain the price of Myrbetriq; only manufacturers of generic mirabegron constrained Astellas from charging even more supracompetitive prices.

264. At all relevant times, Astellas was protected by high barriers to entry, many of which Astellas perpetuated through its conduct. Entering the market for a prescription drug, such as mirabegron, requires large investments of time and money to design, develop, and distribute the drug. Entrants must receive government approval before entry, and, as in this case, generic entrants may face intellectual property challenges that delay or prevent the generic's entry into the market. Astellas manipulated the patent and litigation processes to further increase these barriers to entry and further delay, prevent, and hinder the entry of generic competition. Because of Astellas' unlawful and anticompetitive conduct, Lupin and other generic competitors could not enter the market.

265. The relevant geographic market is the United States and its territories. Astellas held 100% of the mirabegron market share until Lupin and Zydus launched at risk in 2024, and Astellas continues to assert its duplicative patents and actions to increase the cost and attempt to drive competition from the market.

266. To the extent Astellas does not currently have market power because of the at-risk launch of Lupin and Zydus, Astellas is attempting to increase the costs of Lupin and Zydus and to recapture market power in a relevant antitrust market for mirabegron. Astellas is dangerously close to recapturing market power as a result of the unlawful and anticompetitive conduct described in these counterclaims.

EFFECT ON INTERSTATE COMMERCE

267. During the relevant time period, Astellas manufactured, sold, and shipped Myrbetriq in every state in the United States and across state lines in an uninterrupted flow of interstate commerce.

268. As a consequence of Astellas' unlawful and anticompetitive actions, including Astellas' unlawful manipulation of the patent process and Astellas' filing duplicative actions designed to interfere with its competitors, Astellas attempted to, and ultimately succeeded in, monopolizing the market for mirabegron.

269. With monopoly power, Astellas charged supracompetitive prices to patients across the United States.

270. Even after Lupin and other competitors launched at risk, Astellas used its successive actions to increase the cost on Lupin and other competitors, resulting in lower profits and higher cost to market a generic version of mirabegron.

271. During the relevant time period, Astellas used the United States mail, interstate and foreign travel, interstate and foreign wire commerce, and many other means to execute its unlawful and anticompetitive manipulation of the patent and litigation processes. Each named counterdefendant engaged in illegal and anticompetitive conduct, as stated in these

counterclaims, which conduct substantially affected interstate commerce, including commerce in this district.

FIRST COUNTERCLAIM – MONOPOLIZATION UNDER FEDERAL LAW

(15 U.S.C. §§ 2 and 15)

(On behalf of Lupin Ltd. and LPI)

272. Lupin realleges Paragraphs 1–271, as if fully set forth herein.

273. Astellas has monopolized the relevant antitrust market for mirabegron in the United States and has acted with the specific intent to monopolize the market.

274. Astellas possesses market power in the relevant antitrust market for mirabegron.

275. Astellas willfully maintains market power by manipulating the patent process to strategically time the issuance of duplicative patents and by repeatedly filing successive and duplicative patent infringement actions based on patents covering the same or similar subject matter, which actions and patents are designed to interfere with Lupin and other generic manufacturers into the market.

276. Indeed, Astellas' anticompetitive conduct delayed the entry of any generic competition into the market for mirabegron and increased Lupin's cost after entry.

277. Astellas' successive actions are filed without regard to the merit of the action or the patent at-issue.

278. Astellas' serial infringement actions are meritless and objectively baseless because Astellas asserts anticipated or obvious patents based on the same subject matter as earlier-issued patents.

279. Astellas' actions are not brought for a legitimate purpose. Instead, the actions are shams covering Astellas' attempts to interfere with the business operations of Lupin and other

generic competitors in the market for mirabegron. The purpose of the serial actions is to use the process, rather than the underlying merits, to interfere with Lupin and Astellas' other competitors.

280. No reasonable litigant could realistically expect success on the merits of Astellas' serial litigations, especially after several adverse rulings, such as those in Mira II and Mira III.

281. Regardless of the outcome of the pending actions, Astellas will use its pending C and D Family patent applications to strategically time the issuance of future patents that Astellas will assert in future litigation meant to prevent, delay, or hinder generic competition in the market for mirabegron.

282. Through these unlawful activities, including the filing of successive meritless actions, Astellas, in violation of 15 U.S.C. § 2, maintains monopoly power in the market for mirabegron.

283. As a result of Astellas' anticompetitive conduct, Lupin's and other generic manufacturers' entry into the market was delayed, and fewer generic competitors ultimately entered the market.

284. Further, as a result of Astellas' anticompetitive conduct, Astellas has increased the costs of Lupin and other generic competitors that ultimately launched a generic mirabegron drug at risk.

285. Patients and other customers pay more for mirabegron and have fewer choices of mirabegron suppliers because of Astellas' anticompetitive conduct.

286. Because of Astellas' anticompetitive conduct, Lupin has suffered lost profits, lost business opportunities, and attorney fees accrued in defense of Astellas' serial sham litigations. Further, Lupin has suffered damage to its reputation.

SECOND COUNTERCLAIM – ATTEMPTED MONOPOLIZATION UNDER FEDERAL LAW

(15 U.S.C. §§ 2, 15, and 26)

(On behalf of Lupin Ltd. and LPI)

287. Lupin realleges Paragraphs 1–271, as if fully set forth herein.

288. Astellas has attempted to monopolize the relevant antitrust market for mirabegron in the United States and has engaged in anticompetitive conduct with the specific intent to monopolize the market.

289. Astellas has a dangerous probability of achieving monopoly power. Indeed, Astellas' anticompetitive conduct delayed the entry of any generic competition into the market for mirabegron and increased Lupin's cost after entry.

290. The anticompetitive conduct continues to harm Lupin, one of the few generic competitors to risk launching a generic alternative for mirabegron.

291. Astellas attempts to monopolize the market for mirabegron in the United States by manipulating the patent process to strategically time the issuance of duplicative patents and by repeatedly filing duplicative patent infringement actions based on patents covering the same or similar subject matter, which actions and patents are designed to unlawfully interfere with Lupin and other generic mirabegron manufacturers.

292. Astellas' successive actions are filed without regard to the merit of the action or the patent at-issue.

293. Astellas' actions are not brought for a legitimate purpose. Instead, the actions are shams covering Astellas' attempts to interfere with the business operations of Lupin and other generic competitors in the market for mirabegron. The purpose of the serial actions is to use the

process, rather than the underlying merits, to interfere with Lupin and Astellas' other competitors.

294. No reasonable litigant could realistically expect success on the merits of Astellas' serial litigations, especially after several adverse rulings, such as those in Mira II and Mira III.

295. Astellas' serial infringement actions are meritless and objectively baseless because Astellas asserts anticipated or obvious patents based on the same subject matter as earlier-issued patents.

296. Astellas' actions are not brought for a legitimate purpose. Instead, the actions are shams covering Astellas' attempts to interfere with Lupin and other generic competitors in the market for mirabegron.

297. Regardless of the outcome of the pending actions, Astellas will use its pending C and D Family patent applications to strategically time the issuance of future patents that Astellas will assert in future litigation meant to interfere with generic competition in the market for mirabegron.

298. Through these unlawful activities, including the filing of successive meritless actions, Astellas, in violation of 15 U.S.C. § 2, has attempted to monopolize the market for mirabegron.

299. Astellas' anticompetitive conduct impaired the opportunities of potential rivals without furthering competition on the merits.

300. As a result of Astellas' anticompetitive conduct, Lupin's and other generic manufacturers' entry into the market was delayed, and fewer generic competitors ultimately entered the market.

301. Further, as a result of Astellas' anticompetitive conduct, Astellas increased the cost paid by Lupin and other generic manufacturers that launched at risk.

302. Patients and other customers pay more for mirabegron and have fewer choices of mirabegron suppliers because of Astellas' anticompetitive conduct.

303. Because of Astellas' anticompetitive conduct, Lupin has suffered lost profits, lost business opportunities, and attorney fees accrued in defense of Astellas' serial sham litigations. Further, Lupin has suffered damage to its reputation.

THIRD COUNTERCLAIM – MONOPOLIZATION UNDER DELAWARE LAW

(6 Del. Code § 2103)

304. Lupin realleges Paragraphs 1–286, as if fully set forth herein.

305. Astellas has monopolized the relevant antitrust market for mirabegron in Delaware and the United States and has acted with the specific intent to monopolize the market.

306. Astellas possesses market power in the relevant antitrust market for mirabegron.

307. Astellas willfully maintains market power by manipulating the patent process to strategically time the issuance of duplicative patents and by repeatedly filing successive and duplicative patent infringement actions based on patents covering the same or similar subject matter, which actions and patents are designed to interfere with Lupin and other generic manufacturers into the market.

308. Indeed, Astellas' anticompetitive conduct delayed the entry of any generic competition into the market for mirabegron and increased Lupin's cost after entry.

309. Astellas' successive actions are filed without regard to the merit of the action or the patent at-issue.

310. Astellas' serial infringement actions are meritless and objectively baseless because Astellas asserts anticipated or obvious patents based on the same subject matter as earlier-issued patents.

311. Astellas' actions are not brought for a legitimate purpose. Instead, the actions are shams covering Astellas' attempts to interfere with the business operations of Lupin and other generic competitors in the market for mirabegron. The purpose of the serial actions is to use the process, rather than the underlying merits, to interfere with Lupin and Astellas' other competitors.

312. No reasonable litigant could realistically expect success on the merits of Astellas' serial litigations, especially after several adverse rulings, such as those in Mira II and Mira III.

313. Regardless of the outcome of the pending actions, Astellas will use its pending C and D Family patent applications to strategically time the issuance of future patents that Astellas will assert in future litigation meant to prevent, delay, or hinder generic competition in the market for mirabegron.

314. Through these unlawful activities, including the filing of successive meritless actions, Astellas, in violation of 6 Del. Code § 2103(b), maintains monopoly power in the market for mirabegron.

315. As a result of Astellas' anticompetitive conduct, Lupin's and other generic manufacturers' entry into the market was delayed, and fewer generic competitors ultimately entered the market.

316. Further, as a result of Astellas' anticompetitive conduct, Astellas has increased the costs of Lupin and other generic competitors that ultimately launched a generic mirabegron drug at risk.

317. Patients and other customers pay more for mirabegron and have fewer choices of mirabegron suppliers because of Astellas' anticompetitive conduct.

318. Because of Astellas' anticompetitive conduct, Lupin has suffered lost profits, lost business opportunities, and attorney fees accrued in defense of Astellas' serial sham litigations. Further, Lupin has suffered damage to its reputation.

FOURTH COUNTERCLAIM – ATTEMPTED MONOPOLIZATION UNDER DELAWARE LAW

(6 Del. Code § 2103)

319. Lupin realleges Paragraphs 1–271 and 287–303, as if fully set forth herein.

320. Astellas has attempted to monopolize the relevant antitrust market for mirabegron in the United States and has engaged in anticompetitive conduct with the specific intent to monopolize the market.

321. Astellas has a dangerous probability of achieving monopoly power. Indeed, Astellas' anticompetitive conduct delayed the entry of any generic competition into the market for mirabegron and increased Lupin's cost after entry.

322. The anticompetitive conduct continues to harm Lupin, one of the few generic competitors to risk launching a generic alternative for mirabegron.

323. Astellas attempts to monopolize the market for mirabegron in Delaware and the United States by manipulating the patent process to strategically time the issuance of duplicative patents and by repeatedly filing duplicative patent infringement actions based on patents covering the same or similar subject matter, which actions and patents are designed to unlawfully interfere with Lupin and other generic mirabegron manufacturers.

324. Astellas' successive actions are filed without regard to the merit of the action or the patent at-issue.

325. Astellas' actions are not brought for a legitimate purpose. Instead, the actions are shams covering Astellas' attempts to interfere with the business operations of Lupin and other generic competitors in the market for mirabegron. The purpose of the serial actions is to use the process, rather than the underlying merits, to interfere with Lupin and Astellas' other competitors.

326. No reasonable litigant could realistically expect success on the merits of Astellas' serial litigations, especially after several adverse rulings, such as those in Mira II and Mira III.

327. Astellas' serial infringement actions are meritless and objectively baseless because Astellas asserts anticipated or obvious patents based on the same subject matter as earlier-issued patents.

328. Astellas' actions are not brought for a legitimate purpose. Instead, the actions are shams covering Astellas' attempts to interfere with Lupin and other generic competitors in the market for mirabegron.

329. Regardless of the outcome of the pending actions, Astellas will use its pending C and D Family patent applications to strategically time the issuance of future patents that Astellas will assert in future litigation meant to interfere with generic competition in the market for mirabegron.

330. Through these unlawful activities, including the filing of successive meritless actions, Astellas, in violation of 6 Del. Code § 2103(b), has attempted to monopolize the market for mirabegron.

331. Astellas' anticompetitive conduct impaired the opportunities of potential rivals without furthering competition on the merits.

332. As a result of Astellas' anticompetitive conduct, Lupin's and other generic manufacturers' entry into the market was delayed, and fewer generic competitors ultimately entered the market.

333. Further, as a result of Astellas' anticompetitive conduct, Astellas increased the cost paid by Lupin and other generic manufacturers that launched at risk.

334. Patients and other customers pay more for mirabegron and have fewer choices of mirabegron suppliers because of Astellas' anticompetitive conduct.

335. Because of Astellas' anticompetitive conduct, Lupin has suffered lost profits, lost business opportunities, and attorney fees accrued in defense of Astellas' serial sham litigations. Further, Lupin has suffered damage to its reputation.

FIFTH COUNTERCLAIM – UNFAIR COMPETITION UNDER DELAWARE LAW

(On behalf of Lupin Ltd. and LPI)

336. Lupin realleges Paragraphs 1–271, as if fully set forth herein.

337. Lupin reasonably expected to launch, market, and sell a generic version of mirabegron. Lupin reasonably expected to enter business relationships based on its generic version of mirabegron.

338. Astellas' anticompetitive conduct has wrongfully interfered with Lupin's reasonable expectation of selling and entering business relationships based on Lupin's generic version of mirabegron.

339. Astellas' filing successive patent infringement actions based on patents covering the same and similar subject matter is an unfair action designed specifically to prevent, delay, and hinder the entry of generic competition into the market for mirabegron and to raise the costs of any generic competitor that ultimately enters the market for mirabegron.

340. Astellas' unfair action defeated Lupin's reasonable expectation of selling mirabegron and entering business relationships based on its generic version of mirabegron.

341. Astellas' meritless, successive patent-infringement actions delayed Lupin's entry into the market for mirabegron and prevented Lupin from selling its generic version of mirabegron. These successive actions prevented Lupin from legitimately earning revenue in the market for mirabegron.

342. Further, after Lupin's entry, Astellas' anticompetitive and unfair conduct continue to increase Lupin's cost in the market for mirabegron.

343. Astellas has wrongfully interfered with Lupin's business in violation of Delaware unfair competition law.

344. Lupin has suffered harm from, among other things, lost sales, profit, and business opportunities caused by the delayed entry into the market. Further, Lupin continues to suffer harm from defending Astellas' continued filing and litigating meritless, successive actions and from Astellas' accusations that Lupin has infringed Astellas' intellectual property.

SIXTH COUNTERCLAIM – TORTIOUS INTERFERENCE WITH BUSINESS RELATIONS UNDER DELAWARE LAW

(On behalf of Lupin Ltd. and LPI)

345. Lupin realleges Paragraphs 1–271, as if fully set forth herein.

346. When launching a generic version of a drug, Lupin conducts business with, and establishes business relations with, other entities, such as customers, wholesalers, and distributors, in the market for the generic drug.

347. Lupin's relationships with these entities provide future economic benefit for Lupin.

348. When launching its generic version of mirabegron, Lupin had the reasonable probability of conducting business with, and establishing business relations with, entities, including customers, wholesalers, and distributors, in the market for mirabegron.

349. Astellas was aware that Lupin maintained business relationships and business opportunities with entities, such as customers, in the market for mirabegron.

350. Astellas was aware of Lupin's potential to enter or further business relationships through the launch of a generic version of mirabegron.

351. Astellas filed meritless, successive actions with the intent to prevent, delay, and hinder Lupin's entry into the market for mirabegron.

352. Even after Lupin's entry, Astellas continued to file meritless patent infringement actions that raise Lupin's cost and interfere with Lupin's business relations.

353. In violation of Delaware law, Astellas' actions have wrongfully interfered with Lupin's business relationships and opportunities in the market for mirabegron.

354. As a proximate result of Astellas' anticompetitive conduct, Lupin's entry into the mirabegron market was delayed, and Lupin has suffered damages, including lost sales, profits, business opportunities, and business relations.

355. Lupin continues to suffer harm from defending the meritless, successive actions that Astellas wrongfully uses to hinder and harm Lupin and other generic competitors in the market for mirabegron.

SEVENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. Patent No. 10,842,780)

(On behalf of Lupin Ltd.)

356. Lupin Ltd. realleges Paragraphs 1–271, as if fully set forth herein.

357. The manufacture, use, sale, offer for sale, and/or importation of Lupin's ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the C'780 Patent.

358. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin's ANDA Products do not, and will not, infringe any valid and enforceable claims of the C'780 Patent, at least because Lupin's ANDA Products do not meet at least one limitation recited in each and every claim of the C'780 Patent.

EIGHTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. Patent No. 10,842,780)

(On behalf of Lupin Ltd.)

359. Lupin Ltd. realleges Paragraphs 1–271, as if fully set forth herein.

360. The claims of the C'780 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103[15], 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

361. Lupin Ltd. is entitled to a judicial declaration that the claims of the C'780 Patent are invalid.

[15] Lupin will file a Motion to provide relief from the Stipulation And Order Narrowing Issues In Dispute (D.I. 505, "the Stipulation") submitted in this action. Lupin will request that the Court clarify that the Stipulation does not preclude Defendants from presenting obviousness challenges during any future trial or retrial with respect to the '780 patent or alternatively relieve them from the Stipulation and permit Defendants to present their obviousness challenges against the '780 patent at any future trial or retrial.

NINTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. Patent No. 11,707,451)

(On behalf of Lupin Ltd.)

362. Lupin Ltd. realleges Paragraphs 1–271, as if fully set forth herein.

363. The manufacture, use, sale, offer for sale, and/or importation of Lupin's ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the D'451 Patent.

364. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin's ANDA Products do not, and will not, infringe any valid and enforceable claims of the D'451 Patent, at least because Lupin's ANDA Products do not meet at least one limitation recited in each and every claim of the D'451 Patent.

TENTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. Patent No. 11,707,451)

(On behalf of Lupin Ltd.)

365. Lupin Ltd. realleges Paragraphs 1–271, as if fully set forth herein.

366. The claims of the D'451 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

367. Lupin Ltd. is entitled to a judicial declaration that the claims of the D'451 Patent are invalid.

ELEVENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. Patent No. 12,059,409)

(On behalf of Lupin Ltd.)

368. Lupin Ltd. realleges Paragraphs 1–271, as if fully set forth herein.

369. The manufacture, use, sale, offer for sale, and/or importation of Lupin's ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the C'409 Patent.

370. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin's ANDA Products do not, and will not, infringe any valid and enforceable claims of the C'409 Patent, at least because Lupin's ANDA Products do not meet at least one limitation recited in each and every claim of the C'409 Patent.

TWELFTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. Patent No. 12,059,409)

(On behalf of Lupin Ltd.)

371. Lupin Ltd. realleges Paragraphs 1–271, as if fully set forth herein.

372. The claims of the C'409 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

373. Lupin Ltd. is entitled to a judicial declaration that the claims of the C'409 Patent are invalid.

THIRTEENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

(U.S. Patent No. 12,097,189)

(On behalf of Lupin Ltd.)

374. Lupin Ltd. realleges Paragraphs 1–271, as if fully set forth herein.

375. The manufacture, use, sale, offer for sale, and/or importation of Lupin's ANDA Products do not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable claim of the D'189 Patent.

376. Lupin Ltd. is entitled to a judicial determination that the sale, offer for sale, manufacture, importation, and/or use of Lupin's ANDA Products do not, and will not, infringe any valid and enforceable claims of the D'189 Patent, at least because Lupin's ANDA Products do not meet at least one limitation recited in each and every claim of the D'189 Patent.

FOURTEENTH COUNTERCLAIM – DECLARATION OF INVALIDITY

(U.S. Patent No. 12,097,189)

(On behalf of Lupin Ltd.)

377. Lupin Ltd. realleges Paragraphs 1–271, as if fully set forth herein.

378. The claims of the D'189 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 et seq., including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

379. Lupin Ltd. is entitled to a judicial declaration that the claims of the D'189 Patent are invalid.

DEMAND FOR JUDGMENT

Wherefore, Lupin prays for the following relief:

A. That the Court order the Complaint dismissed with prejudice and judgment be entered in favor of Lupin;

B. A judgment in favor of Lupin on each of its defenses;

C. A judgment denying to Astellas any relief whatsoever, including any injunctive relief;

D. A judgment in favor of Lupin on each of its counterclaims;

E. A judgment declaring that Astellas violated 15 U.S.C. § 2 and awarding to Lupin damages or restitution, including treble damages, attorney fees, and prejudgment interest, in an amount proven at trial to be sufficient to compensate Lupin for Astellas' violation of 15 U.S.C. § 2.

F. In accord with 15 U.S.C. § 26, an injunction against Astellas' further asserting against Lupin actions for patent infringement based on Lupin's ANDA products and against Astellas' further alleging that Lupin's ANDA products have infringed Astellas' patents.

G. A judgment declaring that Astellas violated 6 Del. Code § 2103 and awarding to Lupin damages or restitution, attorney fees, costs, and prejudgment interest, in an amount proven at trial to be sufficient to compensate Lupin for Astellas' violation of 6 Del. Code § 2103.

H. A judgment declaring that Astellas engaged in unfair competition under Delaware law; awarding to Lupin damages in an amount to be proven at trial as well as attorney fees and costs; and enjoining Astellas' further alleging that Lupin infringed Astellas' patents for mirabegron.

I. A judgment declaring that Astellas tortiously interfered with Lupin's business relations and prospective business relations; awarding Lupin damages in an amount to be proven at trial as well as attorney fees and costs; and enjoining Astellas' further alleging that Lupin infringed Astellas' patents for mirabegron.

J. A judgment declaring that the manufacture, import, use, sale, and/or offer to sell Lupin's ANDA Products, has not infringed, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid, enforceable claim of U.S. Patent Nos. 10,842,780; 11,707,451; 12,059,409; and 12,097,189;

K. A judgment declaring the claims of U.S. Patent Nos. 10,842,780; 11,707,451; 12,059,409; and 12,097,189 invalid;

L. That the Court declare that Lupin has the lawful right to manufacture, import, use, sell, and/or offer to sell Lupin's ANDA Products in the United States;

M. That Plaintiffs/Counterdefendants and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Lupin or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Lupin, or charging any of them either orally or in writing with infringement of U.S. Patent Nos. 10,842,780, 11,707,451, 12,059,409, and 12,097,189;

N. A judgment declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285 and that Lupin is therefore entitled to recover reasonable attorney fees upon prevailing in this action;

O. That Lupin be awarded costs, attorney fees, and other relief, both legal and equitable, to which it may be justly entitled; and

P. That Lupin be awarded such other and further relief as is just and proper.

Dated: April 4, 2025

Phillips, Mclaughlin & Hall, P.A.

/s/ John C. Phillips, Jr.

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