IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,	)	Case No. 23-819-JFB-CJB
Plaintiffs,	)	**JURY TRIAL DEMANDED**
v.	)	
LUPIN LTD., LUPIN PHARMACEUTICALS, INC., ZYDUS PHARMACEUTICALS (USA) INC., and ZYDUS LIFESCIENCES LIMITED,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

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

THE PARTIES

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

1. Plaintiff Astellas Pharma Inc. ("API") is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

2. Plaintiff Astellas Ireland Co., Ltd. ("AICL") is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown

Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL is a subsidiary of Plaintiff API.

3. Plaintiff Astellas Pharma Global Development, Inc. ("APGD") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062. APGD is a subsidiary of Plaintiff API.

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

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

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

6. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 5801 Pelican Bay Boulevard, Suite 500, Naples, Florida 34108.

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

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

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

9. On information and belief, Zydus Pharmaceuticals (USA) Inc. is in the business of,

inter alia, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in this judicial district.

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

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

NATURE OF ACTION

12. This is an action for patent infringement of United States Patent No. 11,707,451 ("the '451 Patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to the Abbreviated New Drug Applications ("ANDAs") submitted by the above-named Defendants under Section 505(j) of the Federal Food, Drug, And Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking and obtaining United States Food and Drug Administration ("FDA") approval to market generic pharmaceutical products, and the making, using, offering to sell, and/or selling of those generic pharmaceutical products in the United States.

JURISDICTION AND VENUE

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

14. This Court has personal jurisdiction over each Defendant because, *inter alia*, each has committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement by *inter alia*, filing an ANDA, receiving final approval to market generic

mirabegron tablets that are the subject of its ANDAs ("ANDA Products"), and/or launching at risk and making, using, importing, offering for sale and selling each of its ANDA Products throughout the United States and in this judicial district, which will lead to foreseeable and/or actual harm and injury to Plaintiffs.

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

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

17. This Court also has personal jurisdiction over each Defendant because each has frequently availed itself of the legal protections of the State of Delaware, by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

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

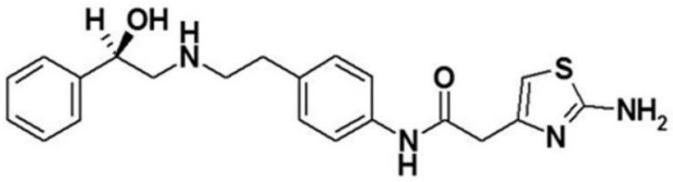
19. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) and/or Fed. R. Civ. P. 4(k)(2).

MYRBETRIQ® TABLETS

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

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

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



23. Myrbetriq® Tablets comprise sustained release hydrogel formulations of mirabegron in a carrier, i.e., contain either 25 mg or 50 mg of mirabegron in extended-release tablets, and provide a continuous drug release of mirabegron for at least 4 hours after oral administration.

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

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

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

THE PATENT-IN-SUIT

27. The United States Patent & Trademark Office ("PTO") duly and legally issued the '451 Patent, entitled "Pharmaceutical Composition for Modified Release," on July 25, 2023. A true and correct copy of the '451 Patent is attached as **Exhibit B**.

28. The '451 Patent generally claims a method for treating overactive bladder such that the treating is with a reduced food effect, comprising administering orally a tablet comprising 10 mg to 200 mg mirabegron in a sustained release formulation that provides a continuous drug release for at least 4 hours after oral administration, wherein the sustained release formulation further comprises a carrier, and wherein the reduced food effect is compared to that after oral administration of an immediate release formulation of mirabegron. Additionally, the claimed methods of treating overactive bladder further anticipate and prevent the occurrence of adverse events, including increase in heart rate caused by mirabegron.

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

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

31. The '451 Patent's pediatric exclusivity will extend to March 28, 2030.

32. AICL is the exclusive licensee of the '451 Patent with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

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

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

35. Myrbetriq® Tablets are covered by one or more claims of the '451 Patent.

36. The '451 Patent was listed in FDA's Orange Book for Myrbetriq® Tablets on August 21, 2023, which was within the 30 day requirement to list newly-issued patents in the Orange Book. *See* 21 C.F.R. § 314.53(d)(1)-(3).

MIRABEGRON ANDA APPLICANTS

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

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

39. On information and belief, each mirabegron ANDA filer was required to run the recommended studies listed in the Mirabegron Guidance in comparison to Myrbetriq Tablets® to meet its bioequivalence requirements for its proposed ANDA product. The Mirabegron Guidance sets a 90% confidence interval "sameness" requirement to establish bioequivalence to Myrbetriq® Tablets. Accordingly, because Myrbetriq® Tablets exhibit a reduced food effect of mirabegron as

compared to an immediate release formulation, on information and belief, each bioequivalent generic mirabegron product will likewise reduce the food effect.

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

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF THE '451 PATENT BY LUPIN

41. Plaintiffs incorporate by reference and reallege paragraphs 1 through 40 above as though fully restated herein.

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

43. Lupin's submission of ANDA No. 209485 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Lupin's ANDA Products, prior to the expiration of the '451 Patent, constitutes infringement of one or more of the claims of the '451 Patent under 35 U.S.C. § 271(e)(2)(A). On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Products infringes one or more claims of the '451 Patent, or their equivalents, at least under 35 U.S.C. §§ 271 (b) and/or (c).

44. By filing ANDA No. 209485, Lupin has necessarily represented to the FDA that

Lupin's ANDA Products have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

45. On information and belief, Lupin's ANDA Products comprise sustained release hydrogel formulations of mirabegron in a carrier, i.e., contain either 25 mg or 50 mg of mirabegron in extended-release tablets, and provide a continuous drug release of mirabegron for at least 4 hours after oral administration.

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

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

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

49. The proposed prescribing information for Lupin's ANDA Products ("Lupin's Label") is substantially identical to that of Myrbetriq® Tablets. *See e.g.*, https://www.lupin.com/US/wp-content/uploads/2024/05/pi-mg-mirabegron-er-tablets-12-2023.pdf, attached as **Exhibit C**.

50. Lupin's Label indicates that Lupin's ANDA Products are approved for treating overactive bladder.

51. Lupin's Label instructs that Lupin's ANDA Products can be taken with or without food.

52. Lupin's Label instructs and encourages healthcare professionals to practice the claimed methods of the '451 Patent.

53. On or about April 20, 2024, Lupin launched its 25 mg ANDA Product, and began making, using, offering to sell, selling and/or importing its 25 mg ANDA Product into the United States.

54. On information and belief, Lupin sells, markets, distributes, and/or imports, or will sell, market distribute and/or import its 25 mg ANDA Product in the United States knowing and intending that physicians, health care professionals, and/or patients prescribe, administer, and/or use Lupin's ANDA Products according to Lupin's instructions and/or Lupin's Label in an infringing manner, and therefore induce or will induce infringement of at least one or more claims of the '451 Patent with the requisite intent under 35 U.S.C. § 271(b).

55. On information and belief, Lupin sells, offers to sell, and/or imports, or will sell, offer to sell, and/or import Lupin's 25 mg ANDA Product with instructions and/or Lupin's Label instructing the use of Lupin's 25 mg ANDA Product in an infringing manner, wherein Lupin's 25 mg ANDA Product is a material part of the claimed invention, wherein Lupin knows that physicians prescribe or will prescribe, healthcare providers administer or will administer, and/or patients use or will use Lupin's 25 mg ANDA Product in accordance with Lupin's provided instructions and/or Lupin's Label, wherein such use directly infringe, or will directly infringe at least one or more claims of the '451 Patent, and wherein generic mirabegron extended-release tablets are not

staple articles or commodities of commerce suitable for substantial non-infringing use. On information and belief, Lupin thus contributes, or will contribute to the infringement of at least one or more claims of the '451 Patent under 35 U.S.C. § 271(c).

56. On information and belief, if Lupin's 50 mg ANDA Product is sold, marketed, distributed, and/or imported in the United States, Lupin knows and intends that physicians, health care professionals, and/or patients will prescribe, administer, and/or use Lupin's 50 mg ANDA Product according to Lupin's instructions and/or Lupin's Label in an infringing manner, and will therefore induce infringement of at least one or more claims of the '451 Patent with the requisite intent under 35 U.S.C. § 271(b).

57. On information and belief, if Lupin's 50 mg ANDA Product is sold, marketed, distributed, and/or imported in the United States, Lupin will sell or offer to sell Lupin's 50 mg ANDA Product with provided instructions and/or Lupin's Label in an infringing manner, wherein Lupin's 50 mg ANDA Product is a material part of the claimed invention, wherein Lupin knows that physicians will prescribe, healthcare providers will administer, and/or patients will use Lupin's 50 mg ANDA Product in accordance with Lupin's provided instructions and/or Lupin's Label, wherein such use will directly infringe at least one or more claims of the '451 Patent, and wherein generic mirabegron extended-release tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. On information and belief, Lupin will thus contribute to the infringement of at least one or more claims of the '451 Patent under 35 U.S.C. § 271(c).

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

59. At least by July 28, 2023, the filing date of the original complaint (D.I. 1), Lupin had actual knowledge of the '451 Patent.

60. Lupin's infringement of the '451 Patent has been willful, as Lupin has been aware of the '451 Patent since July 28, 2023. Lupin's infringement of the '451 Patent by their manufacture, use, offer for sale, sale, or importation of Lupin's 25 mg ANDA Product has been deliberate or intentional.

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

62. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Lupin's 25 mg ANDA Product before the expiration of the '451 Patent will cause and has caused damage to Astellas, entitled Astellas to damages or monetary relief.

63. Astellas has suffered lost profits, and will continue to suffer lost profits for its Myrbetriq® Tablets because of Lupin's infringing acts with respect to Lupin's 25 mg ANDA Products, including sales that would have been made by Plaintiffs that were either lost as a result of Lupin's infringement or were made at eroded prices because of Lupin's infringement. These lost profits have and will also cause a loss in revenue available to Astellas for reinvestment, including, *inter alia*, in research and development opportunities, resulting in long term damage to Astellas' product pipeline and future profits. But for Lupin' infringement, Plaintiffs would not have suffered injury, entitling plaintiffs to damages in the form of lost profits resulting from at least diverted sales and price erosion, future lost profits due to the curtailment of Astellas' research and development programs, and in no event less than a reasonable royalty under 35 U.S.C. § 284.

COUNT II: INFRINGEMENT OF THE '451 PATENT BY ZYDUS

64. Plaintiffs incorporate by reference and reallege paragraphs 1 through 63 above as though fully restated herein.

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

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

67. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Products infringes one or more claims of the '451 Patent, or their equivalents, at least under 35 U.S.C. §§ 271(b) and/or (c). By filing ANDA No. 209488, Zydus has necessarily represented to the FDA that Zydus's ANDA Products have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

68. On information and belief, Zydus's ANDA Products comprise sustained release hydrogel formulations of mirabegron in a carrier, i.e., contain either 25 mg or 50 mg of mirabegron in extended-release tablets, and provide a continuous drug release of mirabegron for at least 4 hours after oral administration.

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

of an immediate release mirabegron formulation.

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

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

72. The proposed prescribing information for Zydus's ANDA Products ("Zydus's Label") is substantially identical to that of Myrbetriq® Tablets. *See e.g.*, https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=2e40eb74-3b2a-47f7-bf31-fe27484f9bd2&type=pdf, **Exhibit D**.

73. Zydus's Label indicates that Zydus's ANDA Products are approved for treating overactive bladder.

74. Zydus's Label instructs that Zydus's ANDA Products can be taken with or without food.

75. Zydus's Label instructs and encourages healthcare professionals to practice the claimed methods of the '451 Patent.

76. Zydus received final FDA approval from FDA for Zydus's ANDA Products on September 29, 2022. *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209488.

77. On April 20, 2024, Zydus launched its ANDA Products, and began making, using,

offering to sell, selling and/or importing its ANDA Products into the United States.

78. On information and belief, Zydus sells, markets, distributes, and/or imports, or will sell, market, distribute and/or import its ANDA Products in the United States knowing and intending that physicians, health care professionals, and/or patients prescribe, administer, and/or use, or will prescribe, administer, and/or use Zydus's ANDA Products according to Zydus's instructions and/or Zydus's Label in an infringing manner, and therefore induce, or will induce infringement of at least one or more claims of the '451 Patent with the requisite intent under 35 U.S.C. § 271(b).

79. On information and belief, Zydus sells or offers to sell, or will sell or offer to sell Zydus's ANDA Products with instructions and/or Zydus's Label instructing the use of Zydus's ANDA Products in an infringing manner, wherein Zydus's ANDA Products are a material part of the claimed invention, wherein Zydus knows that physicians prescribe, or will prescribe, healthcare providers administer, or will administer, and/or patients use, or will use Zydus's ANDA Products in accordance with Zydus's provided instructions and/or Zydus's Label, wherein such use directly infringe, or will directly infringe at least one or more claims of the '451 Patent, and wherein generic mirabegron extended-release tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. On information and belief, Zydus thus contributes, or will thus contribute to the infringement of at least one or more claims of the '451 Patent under 35 U.S.C. § 271(c).

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

81. At least by July 28, 2023, the filing date of the original complaint (D.I. 1), Zydus had actual knowledge of the '451 Patent.

82. Zydus's infringement of the '451 Patent has been willful, as Zydus has been aware

of the ’451 Patent since July 28, 2023. Zydus’s infringement of the ’451 Patent by their manufacture, use, offer for sale, sale, or importation of Zydus’s ANDA Products has been deliberate or intentional.

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

84. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Zydus’s ANDA Products before the expiration of the ’451 Patent will cause and has caused damage to Astellas, entitled Astellas to damages or monetary relief.

85. Astellas has suffered lost profits, and will continue to suffer lost profits for its Myrbetriq® products because of Zydus’s infringing acts with respect Zydus’s ANDA Products, including sales that would have been made by Plaintiffs that were either lost as a result of Zydus’s infringement or were made at eroded prices because of Zydus’s infringement. These lost profits have and will also cause a loss in revenue available to Astellas for reinvestment, including, inter alia, in research and development opportunities, resulting in long term damage to Astellas’ product pipeline and future profits. But for Zydus’ infringement, Plaintiffs would not have suffered injury, entitling plaintiffs to damages in the form of lost profits resulting from at least diverted sales and price erosion, future lost profits due to curtailment of Astellas’ research and development programs, and in no event less than a reasonable royalty under 35 U.S.C. § 284.

JURY DEMAND

86. Plaintiffs respectfully request a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs API, AICL, and APGD, pray for a judgment in their favor

and against Defendants, and respectfully request the following relief:

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

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

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

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

E. An order directing FDA to rescind the final approval of each Defendant's ANDA (i.e., the Lupin ANDA and the Zydus ANDA) and that the effective date of any approval of each Defendants' ANDAs be a date not earlier than the expiration of the '451 Patent;

F. An order requiring each Defendant to take reasonable steps to recall their respective ANDA Products from the market;

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

H. An award of damages pursuant to 35 U.S.C. §§ 271(e) and 284 plus pre-judgment and post-judgment interest;

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

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

Dated: July 23, 2024

OF COUNSEL:

Simon D. Roberts
Jason A. Leonard
Jayita Guhaniyogi
Vincent Li
MCDERMOTT WILL & EMERY
One Vanderbilt Avenue
New York, NY 10017-3852
(212) 547-5400

Connor Romm
MCDERMOTT WILL & EMERY
200 Clarendon Street, Floor 58
Boston, MA 02116-5021
(617) 535-4000

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiffs