IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,	)	C.A. No. 24-939-JFB-EGT
Plaintiffs,	)	**JURY TRIAL DEMANDED**
v.	)	
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.	)	
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, Maharashtra 400055, India, and a manufacturing facility at Nagpur 441 108, Maharashtra, India. On information and belief, Lupin Ltd. is in the business of, *inter alia*, developing, manufacturing, and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 5801 Pelican Bay Boulevard, Suite 500, Naples, Florida 34108. On information and belief, Lupin Pharmaceuticals, Inc. is in the business of, *inter alia*, developing, manufacturing, and/or distributing generic drug products for marketing, sale, and/or use throughout the United States including in this judicial district.

6. By letters dated August 25, 2016, ("Lupin's 2016 Notice Letter") and February 8, 2021 ("Lupin's 2021 Notice Letter"), Lupin notified Plaintiffs that Lupin had submitted to the FDA ANDA No. 209485 for mirabegron "in the form of extended release tablets, each containing 25 mg or 50 mg mirabegron as the active ingredient." ("Lupin ANDA"), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 25 mg and 50 mg strengths ("Lu-

pin's 25 mg ANDA Product" and "Lupin's 50 mg ANDA Product," respectively; together, "Lupin's ANDA Products"). On information and belief, the purpose of Lupin's submission of the Lupin ANDA was to obtain approval under the Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Lupin's ANDA Products prior to midnight on March 28, 2030.

7. In Lupin's 2016 Notice Letter and Lupin's 2021 Notice Letter, Lupin notified Plaintiffs that, as a part of the Lupin ANDA, Lupin had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to some of the then-listed patents in the Orange Book, including with respect to U.S. Patent No. 10,842,780 ("the '780 Patent"), asserting that they are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Lupin's ANDA Products.

8. On November 24, 2020, Astellas brought suit against Lupin, asserting the '780 Patent ("the '780 Case"). (*See Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589 (D. Del.), D.I. 1.)

9. In its Answer, Lupin did not dispute personal jurisdiction or venue in the '780 Case. (*See Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589 (D. Del.), D.I. 47 at ¶¶ 94-98.)

10. On September 28, 2022, Lupin received final FDA approval for the Lupin ANDA (*see* **Exhibit B**, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/209485Orig1s000ltr.pdf) to market Lupin's 25 mg ANDA Product and Lupin's 50 mg ANDA Product. Lupin since commercially launched its 25 mg ANDA Product on April 19, 2024 and Lupin's 50 mg ANDA Product on September 3, 2024. (*See* **Exhibit C**, available at https://www.lupin.com/lupin-launches-mirabegron-extended-release-tablets-in-the-united-states/;

Exhibit D at 38-39, available at https://dailymed.nlm.nih.gov/dailymed/get-File.cfm?setid=d22d3d12-8466-46db-bc19-d13e87c6115c&type=pdf; **Exhibit K**, available at https://www.lupin.com/lupin-launches-mirabegron-extended-release-tablets-in-the-united-states-2/.) Lupin's Package Insert, revised September 2024, ("Lupin's Label") was submitted to the FDA. (*See* **Exhibit D**.) The Lupin Label is available on the government website DailyMed.nlm.nih.gov, which is operated by the National Library of Medicine, National Institutes of Health. (S*ee* **Exhibit E**, available at https://dailymed.nlm.nih.gov/dailymed/about-dailymed.cfm.) The DailyMed web-site explains that "[t]he labeling on DailyMed is the most recent submitted labeling to the FDA by companies and currently in use." (*See id.*)

11. The Lupin Label, as submitted to the FDA, reports the "Marketing Start Date" for Lupin's 25 mg ANDA Product as April 19, 2024 and the "Marketing Start Date" for Lupin's 50 mg ANDA Product as September 3, 2024. (**Exhibit D** at 38, 39.)

12. Lupin, *inter alia*, through its website, advertises that it is marketing 25 mg and 50 mg "Mirabegron Extended-Release Tablets" in pack sizes of 30 and 90 tablets and that those tablets are AB rated to "RLD/Brand Name: Myrbetriq®". (*See* **Exhibit F**, available at https://www.lupin.com/US/product/mirabegron-extended-release-tablets/.) Lupin also provides a link to "Download Safety Data Sheet," which identifies the manufacturer of Lupin's ANDA Products as Lupin Limited and Lupin Pharmaceuticals, Inc. (*See* **Exhibit G**, available at https://www.lupin.com/US/wp-content/uploads/2024/05/sds-mirabegron-er-tablets-jan-2024.pdf.) On information and belief, the 25 mg "Mirabegron Extended-Release Tablets" in pack sizes of 30 and 90 tablets are Lupin's 25 mg ANDA Product and Lupin is manufacturing, importing, offering for sale and selling Lupin's 25 mg ANDA Product under the Lupin ANDA and the 50 mg "Mirabegron Extended-Release Tablets" in pack sizes of 30 and 90 tablets are Lupin's 50 mg ANDA Product

and Lupin is manufacturing, importing, offering for sale and selling Lupin's 50 mg ANDA Product under the Lupin ANDA. (*See id.*; **Exhibit F**.).

13. On information and belief, and consistent with their past practices, Lupin Ltd. and Lupin Pharmaceuticals, Inc. acted collaboratively in the preparation and submission of ANDA No. 209485, and the making, using, selling, offering to sell, and/or importing of some or all of its ANDA Products.

14. On information and belief, and consistent with their past practices, Lupin Ltd. and Lupin Pharmaceuticals, Inc. worked, and will work, in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 209485 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

NATURE OF ACTION

15. This is an action for patent infringement of United States Patent No. 12,059,409 ("the '409 Patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to the ANDA submitted by Lupin under Section 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking and obtaining 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

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

17. This Court has personal jurisdiction over each Defendant because, among other things, each Defendant 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 ANDA, and/or making, using, importing, offering for sale, and selling its ANDA Products which will lead to foreseeable harm and injury to Plaintiffs.

18. This Court also has personal jurisdiction over Lupin Pharmaceuticals, Inc. by virtue of Lupin Pharmaceuticals, Inc.'s incorporation in the State of Delaware. Further, each Defendant's affiliations with the State of Delaware are so continuous and systematic as to render each Defendant essentially at home in this forum, and Lupin Ltd. is a foreign defendant that is not subject to jurisdiction in any state's courts of general jurisdiction, making this Court a proper venue for personal jurisdiction.

19. The Court also has personal jurisdiction over each Defendant because, *inter alia*, each Defendant 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.

20. This Court also has personal jurisdiction over each Defendant because each Defendant 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. (*See, e.g.*, *Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589 (D. Del.), D.I. 47; *Vertex Pharmaceuticals Incorporated v. Lupin Limited et al.*, C.A. No. 22-966 (D. Del.), D.I. 12.)

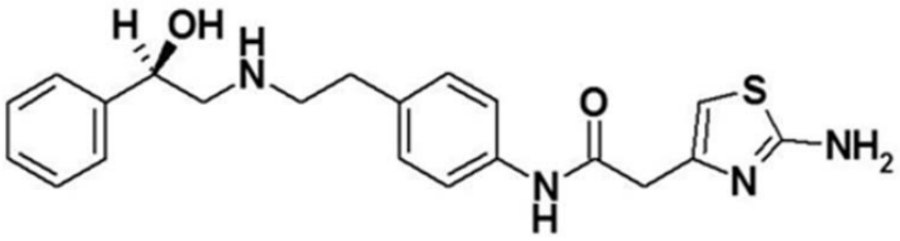
21. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over each Defendant.

22. 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

23. APGD holds approved New Drug Application ("NDA") No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient, mirabegron. The FDA approved NDA No. 202611 on June 28, 2012 for both the 25 mg and 50 mg extended-release Myrbetriq® tablets.

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



25. Myrbetriq® extended-release tablets, containing 25 mg or 50 mg of mirabegron ("Myrbetriq® Tablets"), are indicated for the treatment of overactive bladder ("OAB") with symptoms of urge urinary incontinence, urgency, and urinary frequency.

26. Myrbetriq® Tablets comprise a sustained release hydrogel-forming formulation containing, *inter alia*, polyethylene oxide and polyethylene glycol as inactive ingredients within the tablet formulation, which function as a hydrogel-forming polymer and an additive, respectively.

27. For quality control purposes in the U.S. market, Myrbetriq® Tablets are subjected to dissolution testing using the United States Pharmacopeia ("USP") Apparatus I. A dissolution test evaluates the rate and extent that a compound dissolves under carefully controlled conditions. Within the context of regulatory approval, the USP dissolution test helps safeguard against the release of drug products that do not perform acceptably. USP Apparatus I (basket) and II (paddle) provide a platform to evaluate the in vitro performance of dosage forms using standardized conditions. These two apparatus, and associated procedures, have become widely used and accepted.

28. When measured in accordance with the United States Pharmacopeia ("USP") dissolution apparatus II, using 900 mL of USP buffer and having a pH of 6.8 at a paddle rotation speed of 200 rpm, the Myrbetriq® Tablets release 39% or less of mirabegron after 1.5 hours, and at least 75% of mirabegron after 7 hours.

PRIOR MYRBETRIQ® LITIGATION WITH LUPIN

29. Within 45 days of receipt of Lupin's 2016 Notice Letter, Astellas initiated a suit for infringement, asserting some of the then-listed patents in the Orange Book for Myrbetriq® Tablets, United States Patent Nos. 7,342,117, 7,982,049, 8,835,474, and RE44,872 against Lupin. (*Astellas*

Pharma Inc. et al. v. Lupin Ltd. et al., C.A. No. 16-908 (D. Del.), D.I. 1.) Astellas reached a settlement with Lupin, and Astellas' suit against Lupin concluded. (*Astellas Pharma Inc. et al. v. Actavis Elizabeth LLC et al*., C.A. No. 16-905 (Cons.) (D. Del.), D.I. 582.)

30. On November 24, 2020, the '780 Patent issued, and Astellas brought suit against Lupin asserting the '780 Patent on the same day. (*Astellas Pharma Inc. et al. v. Sandoz Inc.*, C.A. No. 20-1589 (D. Del.), D.I. 1.) The '780 Patent was timely listed in the Orange Book for Myrbetriq® Tablets. Litigation in the '780 Case between Astellas and Lupin is ongoing.

31. Prior to the trial in the '780 Case, Lupin stipulated that Lupin's ANDA Products would infringe every limitation of Claims 5, 20, and 25 of the '780 Patent ("Asserted Claims of the '780 Patent") with the exception of a limitation reciting "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" ("Dissolution Limitation of the '780 Patent"). (*See Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589 (D. Del.), D.I. 517 at 1-3 (attached as **Exhibit H**).)

32. The prior suits did not involve the '409 Patent because, *inter alia*, they were filed prior to the issuance of the '409 Patent.

33. On April 19, 2024, Lupin commercially launched Lupin's 25 mg ANDA Product and continues to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's 25 mg ANDA Product prior to the expiration of the'409 Patent and the associated pediatric exclusivity period. (*See* **Exhibit D** at 38.)

34. On September 3, 2024, Lupin commercially launched Lupin's 50 mg ANDA Product and continues to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's 50 mg ANDA Product prior to the expiration of the '409 Patent and the associated pediatric exclusivity period. (*See id.* at 39.)

THE PATENT-IN-SUIT

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

36. Plaintiffs listed the '409 Patent for Myrbetriq® Tablets in FDA's Orange Book on August 28, 2024, 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).)

37. The '409 Patent generally claims tablet formulations of mirabegron comprising certain excipients and possessing certain dissolution profiles. Independent Claim 1 of the '409 Patent recites "[a] tablet comprising 10 mg to 200 mg of [mirabegron], or a pharmaceutically acceptable salt thereof, in a sustained release hydrogel-forming formulation comprising a hydrogel-forming polymer having an average molecular weight of 200,000 to 7,000,000 and an additive having a water solubility of at least 0.1 g/mL at 20±5 °C." Claim 1 further requires that the "hydrogel-forming polymer is polyethylene oxide" and that the recited "additive is polyethylene glycol." In addition, Claim 1 recites "wherein a drug dissolution rate from the 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" ("Dissolution Limitation of the '409 Patent").

38. The dissolution conditions and requirements specified in the Dissolution Limitation of the ’409 Patent are identical to those in the Dissolution Limitation of the ’780 Patent.

39. API is the record owner and assignee of the ’409 Patent.

40. The ’409 Patent will expire no earlier than September 28, 2029 and retains FDA pediatric exclusivity through midnight on March 28, 2030.

41. AICL is the exclusive licensee of the ’409 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.

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

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

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

MIRABEGRON ANDA FILERS

45. In June 2013, FDA issued a notice in the Federal Register (78 Fed. Reg. 37230 at 30-31 (June 20, 2013)) regarding bioequivalence guidance to be published on its website for mirabegron ANDAs. On its website, FDA lists the following dissolution requirements for mirabegron ANDA filers in order to establish bioequivalence with Myrbetriq® Tablets (“Mirabegron Bioequivalence Guidance”):

Drug Name	Dosage Form	USP Apparatus	Speed (RPMs)	Medium	Volume (mL)	Recommended Sampling Times (minutes)	Date Updated
Mirabegron	Tablet (Extended Release)	I (Basket)	100	Phosphate Buffer, pH 6.8	900	1, 3, 5, 7, 8.5, 10 and 12 hours	05/09/2013

46. On information and belief, each mirabegron ANDA filer will be required to meet this dissolution method, or an equivalent dissolution method, to meet its bioequivalence requirements for its proposed ANDA products using Myrbetriq® Tablets as the reference standard. On information and belief, a proposed mirabegron ANDA product will have equivalent dissolution properties to Myrbetriq® Tablets as measured by USP Apparatus I and II.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF THE '409 PATENT

47. Plaintiffs incorporate by reference and reallege paragraphs 1 through 46 above as though fully restated herein.

48. 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 '409 Patent, constitutes infringement of at least Claim 1 of the '409 Patent under 35 U.S.C. § 271(e)(2)(A).

49. Lupin, by filing ANDA No. 209485, 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. (**Exhibit D** at 1, 3-5.)

50. On September 28, 2022, Lupin received final approval from the FDA for Lupin's ANDA Products. In Lupin's ANDA Approval Letter, the FDA stated that it has "determined [Lupin's ANDA Products] to be bioequivalent and therapeutically equivalent to the reference listed

drug (RLD), [Myrbetriq® Tablets] … of [Astellas]." (*See* **Exhibit B** at 1.). On information and belief, FDA relied on, *inter alia*, Lupin's dissolution data to conclude that Lupin's ANDA Products are bioequivalent to Astellas' Myrbetriq® Tablets.

51. In the '780 Case, Lupin stipulated that Lupin's ANDA Products: (1) "are sustained-release hydrogel-forming pharmaceutical compositions in the form of a tablet," and (2) "comprise . . . a means for forming a hydrogel." (**Exhibit H** at 2.)

52. In the '780 Case, Lupin stipulated that Lupin's ANDA Products met the following claim elements: (1) "10 mg to 200 mg of [mirabegron], or a pharmaceutically acceptable salt thereof;" (2) "a hydrogel-forming polymer having an average molecular weight of 100,000 to 8,000,000;" and (3) "an additive having a water solubility of at least 0.1 g/mL at 20±5 °C". (**Exhibit H** at 3; '780 Patent at 20:19-26.)

53. Lupin's ANDA Products comprise tablets containing either 25 mg or 50 mg of mirabegron. (**Exhibit D** at 1; **Exhibit H** at 1.)

54. Lupin's ANDA Products use a sustained release hydrogel-forming formulation and contain, *inter alia*, polyethylene oxide and polyethylene glycol as inactive ingredients within the tablet. (**Exhibit D** at 14; *see also* **Exhibit I** (*Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589 (D. Del.), D.I. 527 excerpt) at 599:20-600:14; **Exhibit H** at 2.)

55. The polyethylene oxide and polyethylene glycol in Lupin's ANDA Products function as a hydrogel-forming polymer and an additive, respectively, as claimed in Claim 1 of the '409 Patent. (*See* **Exhibit I** (*Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589 (D. Del.), D.I. 529, 530 excerpts) at 1194:15-21.)

56. The grade of polyethylene oxide used in Lupin's ANDA Products has an average molecular weight of 1,000,000. (*See* **Exhibit D** at 38, 39.) Therefore, the polyethylene oxide used

in Lupin's ANDA Products has "average molecular weight of 200,000 to 7,000,000" as claimed in Claim 1 of the '409 Patent.

57. Lupin's ANDA Products contain polyethylene glycol 6000 (PEG 6000) as an additive. (**Exhibit D** at 38, 39.) PEG 6000 has "a water solubility of at least 0.1 g/mL at 20±5 °C" as claimed in Claim 1 of the '409 Patent. (**Exhibit H** at 3;'780 Patent at 20:25-26; '409 Patent at Claim 1.)

58. On information and belief, and as required by the Mirabegron Bioequivalence Guidance, Lupin uses the dissolution method (or its equivalent) to establish Lupin's ANDA Products are bioequivalent to Myrbetriq® Tablets. On information and belief, Lupin's ANDA Products will have equivalent dissolution properties, as measured by USP Apparatus I and II, to Myrbetriq® Tablets, which use a hydrogel formulation.

59. When tested according to the conditions specified in the Dissolution Limitation of the '409 Patent, the drug release profiles of expired samples of Lupin's 50 mg ANDA Product met the Dissolution Limitation of the '409 Patent. (*Astellas Pharma Inc. v. Sandoz Inc.*, C.A. No. 20-1589 (D. Del.), D.I. 536 at ¶¶ 216-218.)

60. On or about April 19, 2024, Lupin commercially launched Lupin's 25 mg ANDA Product, and continues to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's 25 mg ANDA Product prior to the expiration of the '409 Patent.. (**Exhibit D** at 38.)

61. On or about September 3, 2024, Lupin commercially launched Lupin's 50 mg ANDA Product, and continues to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's 50 mg ANDA Product prior to the expiration of the '409 Patent. (**Exhibit D** at 39.)

62. On information and belief, because of the dissolution requirements contained within the Mirabegron Bioequivalence Guidance, including the use of Myrbetriq® Tablets as the reference standard, Lupin's ANDA Product uses a hydrogel formulation, the same as or equivalent to the Myrbetriq® Tablets formulation, that is covered by one or more claims of the '409 Patent.

63. Lupin has infringed at least Claim 1 of the '409 Patent under 35 U.S.C. § 271(a) by the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Products in the United States.

64. Samples of Lupin's 25 mg ANDA Product that were used in its April 19, 2024 commercial launch were tested using the same conditions specified in the Dissolution Limitation of the '409 Patent and found to meet that limitation by releasing 39% or less mirabegron after 1.5 hours and at least 75% mirabegron after 7 hours. (Results from Pace Laboratories (attached as **Exhibit J**).)

65. Samples of Lupin's 50 mg ANDA Product that were used in its September 3, 2024 commercial launch were tested using the same conditions specified in the Dissolution Limitation of the '409 Patent and found to meet that limitation by releasing 39% or less mirabegron after 1.5 hours and at least 75% mirabegron after 7 hours. (Results from Pace Laboratories (attached as **Exhibit L**).)

66. On information and belief, by beginning and/or continuing Lupin's making, using, selling, offering to sell, and/or importing Lupin's ANDA Products after the filing and service of the original complaint (D.I. 1), Lupin did so despite an objectively high likelihood that its actions constituted infringement of a valid patent. On information and belief, Lupin actually knew, or it was so obvious that Lupin should have known but for its willful blindness, that its actions constituted infringement of a valid patent. On information and belief, Lupin's infringement is willful.

67. Unless Lupin is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Lupin's infringement of the '409 Patent. Plaintiffs do not have an adequate remedy at law.

68. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Lupin's ANDA Products before the expiration of the '409 Patent and the pediatric exclusivity period associated with it will cause and has caused damage to Astellas, entitling Astellas to damages or monetary relief.

69. 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 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's 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.

JURY DEMAND

70. 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 Lupin, and respectfully request the following relief:

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

B. A judgment that Lupin's making, using, offering to sell, or selling in the United States or importing into the United States of Lupin's 25 mg ANDA Product infringes the '409 Patent;

C. A judgment that Lupin's making, using, offering to sell, or selling in the United States or importing into the United States of Lupin's 50 mg ANDA Product infringes the '409 Patent;

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

E. An order pursuant to pursuant to 35 U.S.C. § 271(e)(4)(A) directing FDA to rescind the final approval of Lupin's ANDA and that the effective date of any approval of Lupin's ANDA be a date not earlier than midnight on March 29, 2030 corresponding to the expiration of the pediatric exclusivity associated with the '409 Patent, including any extensions and/or other periods of exclusivity to which Plaintiffs and/or the '409 Patent are or become entitled;

F. An order requiring Lupin to take reasonable steps to recall Lupin's ANDA Products from the market;

G. An award of damages pursuant to 35 U.S.C. §§ 271(e)(4) and/or 284 plus pre-judgment and post-judgment interest, including a trebling of damages for Lupin's willful infringement;

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

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

Dated: November 4, 2024

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

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
simonroberts@mwe.com
jleonard@mwe.com
jguhaniyogi@mwe.com
vli@mwe.com

Samoneh Schickel
MCDERMOTT WILL & EMERY
300 Colorado Street, Suite 2200
Austin, TX 78701
(512) 726-2600
sschickel@mwe.com

James F. Hurst, P.C.
Bryan S. Hales
KIRKLAND & ELLIS LLP
333 West Wolf Point Plaza
Chicago, IL 60654
(312) 862-2000
james.hurst@kirkland.com
bryan.hales@kirkland.com

Jeanna M. Wacker
Ashley Ross
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
jeanna.wacker@kirkland.com
ashley.ross@kirkland.com

Diva Hollis
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 380-5000
diva.hollis@kirkland.com