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. _____
Plaintiffs,	)	**JURY TRIAL DEMANDED**
v.	)	
ZYDUS PHARMACEUTICALS (USA) INC. and ZYDUS LIFESCIENCES LIMITED	)	
Defendants.	)	

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

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

5. 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, Gujarat 382481, India. On information and belief, Zydus Lifesciences Limited 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 September 6, 2016 ("Zydus's 2016 Notice Letter"), July 6, 2018 ("Zydus's 2018 Notice Letter"), and March 3, 2021 ("Zydus's 2021 Notice Letter"), Zydus notified Plaintiffs that Zydus had submitted to the FDA ANDA No. 209488 for mirabegron extended-release oral tablets, 25 mg, 50 mg ("Zydus ANDA"), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 25 mg and 50 mg strengths ("Zydus's 25

mg ANDA Product" and "Zydus's 50 mg ANDA Product," respectively; together, "Zydus's ANDA Products"). On information and belief, the purpose of Zydus's submission of the Zydus 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 Zydus's ANDA Products at least prior to midnight on March 28, 2030.

7. In Zydus's 2016 Notice Letter, Zydus's 2018 Notice Letter, and Zydus's 2021 Notice Letter, Zydus notified Plaintiffs that, as a part of the Zydus ANDA, Zydus 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 Zydus's ANDA Products.

8. On November 24, 2020, Astellas brought suit against Zydus, 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, Zydus 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. 60 at ¶¶ 94-98.

10. On September 29, 2022, Zydus received final FDA approval for the Zydus ANDA (*see* **Exhibit B**, available at https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=209488#42081) to market Zydus's 25 mg ANDA Product and Zydus's 50 mg ANDA Product. Zydus since commercially launched its ANDA Products on April 19, 2024. (*See* **Exhibit C**,

available at https://www.biospace.com/zydus-launches-mirabegron-extended-release-tablets-in-the-us.) Zydus's Package Insert, revised February 2024, ("Zydus's Label") was submitted to the FDA. (*See* **Exhibit D**, available at https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=2e40eb74-3b2a-47f7-bf31-fe27484f9bd2&type=pdf.) The Zydus 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 website explains that "[t]he labeling on DailyMed is the most recent submitted labeling to the FDA by companies and currently in use." (*See id.*) The DailyMed's profile for Zydus's mirabegron tablets is also accessible via Zydus's website at a link labeled "PRESCRIBING INFORMATION (INCLUDING ANY BOXED WARNINGS)." (*See* **Exhibit F**, available at Search Results for "Mirabegron" at https://zydususa.com/generic-products/.)

11. The Zydus Label, as submitted to the FDA, reports the "Marketing Start Date" for Zydus's 25 mg ANDA Product and Zydus's 50 mg ANDA Product as January 23, 2024. (**Exhibit D** at 35, 36.)

12. Zydus, *inter alia*, through its website, advertises that it is marketing 25 mg and 50 mg "Mirabegron ER Tablets" and that those tablets are AB rated to "Brand Equivalent: Myrbetriq®". (*See* **Exhibit F**, available at Search Results for "Mirabegron" at https://zydususa.com/generic-products/.) Zydus's Label also identifies the manufacturer of Zydus's ANDA Products as Zydus Lifesciences Limited. (*See* **Exhibit D** at 29.) The distributor of Zydus's ANDA Products is identified by Zydus's Label as Zydus Pharmaceuticals (USA) Inc. (*See id.* at 30.) On information and belief, the 25 mg and 50 mg "Mirabegron ER Tablets" on Zydus's website are Zydus's 25 mg and 50 mg ANDA Products and Zydus is manufacturing, importing,

offering for sale and selling Zydus's ANDA Product under the Zydus ANDA. (*See* **Exhibit F**; **Exhibit D** at 29-30.)

13. On information and belief, and consistent with their past practices, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited acted collaboratively in the preparation and submission of ANDA No. 209488, 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, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited have 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. 209488 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 Zydus 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 and 1338(a).

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. 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 Zydus Lifesciences Limited 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.*, *Acadia Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, C.A. No. 20-1021 (D. Del.), D.I. 9.)

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.

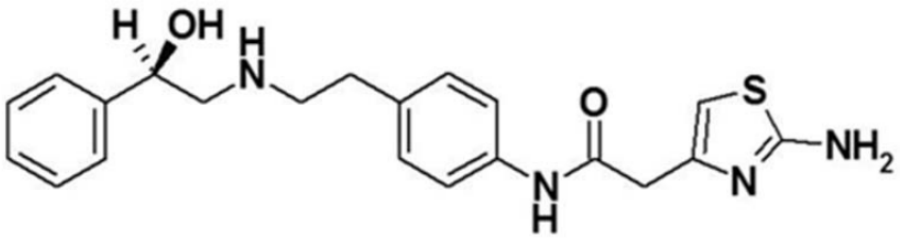
22. Zydus has litigated multiple cases relating to its ANDA Products in the United States District Court for the District of Delaware, and Zydus has not challenged venue as improper in any of those cases. (*See Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA), Inc. et al.*, C.A. No. 16-924 (D. Del.), D.I. 18 at ¶ 19; *Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589 (D. Del.), D.I. 60 at ¶ 98; *Astellas Pharma Inc. et al. v. Lupin Ltd. et al.*, C.A. No. 23-819 (D. Del.), D.I. 20 at ¶ 21.)

23. 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

24. 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.

25. 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:



26. 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.

27. 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.

28. 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.

29. 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 ZYDUS

30. Within 45 days of receipt of Zydus'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 Zydus.

(*Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA), Inc. et al.*, C.A. No. 16-924 (D. Del.), D.I. 1.) Astellas reached a settlement with Zydus, and Astellas' suit against Zydus concluded. (*Astellas Pharma Inc. et al. v. Actavis Elizabeth LLC et al.*, C.A. No. 16-905 (Cons.) (D. Del.), D.I. 536.)

31. On November 24, 2020, the '780 Patent issued, and Astellas brought suit against Zydus 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 Zydus is ongoing.

32. Prior to the trial in the '780 Case, Zydus stipulated that Zydus'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" ("the 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. 516 at 2-3 (attached as **Exhibit G**).)

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

34. On or about April 19, 2024, Zydus commercially launched its ANDA Products and continues to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Products prior to the expiration of the'409 Patent and the associated pediatric exclusivity period. (**Exhibit C**.)

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 will list the '409 Patent for Myrbetriq® Tablets in the FDA's Orange Book no later than September 12, 2024, which is within the 30-day requirement to list newly-issued patents in the Orange Book. (*See* 21 C.F.R. § 314.53(d)(1)-(3).)

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.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF THE ’409 PATENT

45. Plaintiffs incorporate by reference and reallege paragraphs 1 through 44 above as though fully restated herein.

46. 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 ’409 Patent, constitutes infringement of at least Claim 1 of the ’409 Patent under 35 U.S.C. § 271(e)(2)(A).

47. Zydus’s ANDA Products have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets. (**Exhibit D** at 1, 3-4.)

48. In the ’780 Case, Zydus stipulated that Zydus’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 G** at 2.)

49. In the ’780 Case, Zydus stipulated that Zydus’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 G** at 3; ’780 Patent at 20:19-26.)

50. Zydus’s ANDA Products comprise tablets containing either 25 mg or 50 mg of mirabegron. (**Exhibit D** at 1; **Exhibit G** at 1.)

51. Zydus’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 13; *see also* **Exhibit H** (*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 G** at 2.)

52. The polyethylene oxide and polyethylene glycol in Zydus’s ANDA Products function as a hydrogel-forming polymer and an additive, respectively, as claimed in Claim 1 of the ’409 Patent. (*See* **Exhibit H** (*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.)

53. The grades of polyethylene oxide used in Zydus’s ANDA Products have an average molecular weight of 200,000 and 2,000,000, respectively. (*See* **Exhibit D** at 34-36.) Therefore, each grade of polyethylene oxide used in Zydus’s ANDA Products has “an average molecular weight of 200,000 to 7,000,000” as claimed in Claim 1 of the ’409 Patent.

54. Zydus’s ANDA Products contain polyethylene glycol 6000 (PEG 6000) and polyethylene glycol 8000 (PEG 8000), which function as additives. (**Exhibit D** at 34-36.) PEG 6000 and PEG 8000 each have “a water solubility of at least 0.1 g/mL at 20±5 °C” as claimed in Claim 1 of the ’409 Patent. (**Exhibit G** at 3;’780 Patent at 20:25-26; ’409 Patent at Claim 1.)

55. Zydus received final FDA approval from the FDA for Zydus's ANDA Products on September 29, 2022. (*See* **Exhibit B**.)

56. On or about April 19, 2024, Zydus commercially launched Zydus's ANDA Products and continues to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Products prior to the expiration of the '409 Patent. (**Exhibit C**.)

57. Zydus 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 Zydus's ANDA Products in the United States.

58. Samples from commercial batches of Zydus's ANDA Products 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. (Dissolution Results (attached as **Exhibit I**).)

59. On information and belief, if Zydus continues making, using, selling, offering to sell, and/or importing any of Zydus's ANDA Products after the filing and service of this complaint, Zydus will do so despite an objectively high likelihood that its actions constitute infringement of a valid patent. On information and belief, Zydus actually will know, or it will be so obvious that Zydus should have known but for its willful blindness, that its actions constitute infringement of a valid patent. On information and belief, Zydus's infringement will therefore be willful.

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

61. 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 '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.

62. Astellas has suffered lost profits and will continue to suffer lost profits for its Myrbetriq® Tablets because of Zydus's infringing acts with respect to 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'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

63. 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 Zydus, and respectfully request the following relief:

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

B. A judgment that Zydus's making, using, offering to sell, or selling in the United States or importing into the United States of its ANDA Products infringes the '409 Patent;

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Zydus, 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 Zydus'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;

D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) directing the FDA to rescind the final approval of Zydus's ANDA and that the effective date of any approval of Zydus'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;

E. An order requiring Zydus to take reasonable steps to recall its ANDA Products from the market;

F. 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 Zydus's willful infringement;

G. 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

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

Dated: August 13, 2024

MCCARTER & ENGLISH, LLP

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