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Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., and BAUSCH HEALTH COMPANIES INC., Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA), INC., ZYDUS WORLDWIDE DMCC, and ZYDUS LIFESCIENCES LIMITED, Defendants.	Case No.: _____

COMPLAINT

Plaintiff Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd. and Bausch Health Companies Inc. (collectively, "Salix"), by their attorneys, Morgan, Lewis & Bockius LLP, file this Complaint for patent infringement against Zydus Pharmaceuticals (USA), Inc., Zydus

Worldwide DMCC, and Zydus Lifesciences Limited (collectively, "Zydus") and hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Zydus's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of COLAZAL® (balsalazide disodium capsules, 750 mg) prior to the expiration of U.S. Patent Nos. 7,452,872 ("the '872 patent"), 7,625,884 ("the '884 patent"), and 8,497,256 ("the '256 patent") (collectively, the "patents-in-suit").

2. Zydus Pharmaceuticals (USA) Inc., on behalf of Zydus Worldwide DMCC, notified Salix by letter dated August 1, 2022 ("Notice Letter") that it had submitted to FDA ANDA No. 217592 ("Zydus's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of generic balsalazide disodium 750 mg capsules (the "ANDA Product") under 21 U.S.C. § 355 (j) prior the expiration of the patents-in-suit. The Notice Letter stated that Zydus has received a Paragraph IV acceptance acknowledgement receipt letter from FDA.

3. The Notice Letter stated that Zydus's ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") regarding the '872 patent and the '884 patent.

PARTIES

4. Plaintiff Salix Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

5. Plaintiff Salix Pharmaceuticals, Ltd. is a corporation organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

6. Plaintiff Bausch Health Companies Inc. is a company organized and existing under the laws of Canada, having its United States headquarters at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

7. Upon information and belief, defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of New Jersey with its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. Upon information and belief, Zydus Worldwide DMCC is a company organized and existing under the laws of the United Arab Emirates with its principal place of business at Armada Tower 2, P2, Cluster P, 9 Floor, Office 908, Al Thanyah 5, Hadaeq Mohammed Bin Radhid, Dubai, United Arab Emirates. Upon information and belief, Zydus Worldwide DMCC is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

9. Upon information and belief, defendant Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited) is a company organized and existing under the laws of the

Republic of India, with its principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vashnodevi Circle, S.G. Highway, Ahmedabad 382 481, India. Upon information and belief, Zydus Lifesciences Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC.

10. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC are wholly owned indirect subsidiaries of Zydus Lifesciences Limited.

11. Upon information and belief, Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Zydus Lifesciences Limited acted in concert to prepare and submit Zydus's ANDA to FDA.

12. Upon information and belief, Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Zydus Lifesciences Limited know and intend that upon approval of Zydus's ANDA, Zydus Lifesciences limited will manufacture the ANDA Product and Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC will directly or indirectly market, sell, and distribute the ANDA Product throughout the United States, including in New Jersey. Upon information and belief, Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Zydus Lifesciences Limited are agents of each other and/or operate in concert as integrated parts of the same business group, including regarding the ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Zydus Lifesciences Limited and Zydus Pharmaceuticals (USA) Inc. participated in, assisted, and cooperated with Zydus Worldwide DMCC in the acts complained of herein.

13. Upon information and belief, following any FDA approval of Zydus's ANDA, Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Limited, and Zydus Worldwide DMCC will act in concert to distribute and sell the ANDA Product throughout the United States, including within New Jersey.

JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

15. Zydus Pharmaceuticals (USA) Inc. is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey and therefore transacts business within New Jersey related to Salix's claims, and/or has engaged in systematic and continuous business contacts within New Jersey.

16. Zydus Worldwide DMCC is subject to personal jurisdiction in New Jersey because among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Worldwide DMCC develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey,

and therefore transacts business related to Salix's claims, and/or has engaged in systematic and continuous business contacts within New Jersey. On information and belief, Zydus Worldwide consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Almirall, LLC v. Zydus Pharms. (USA) Inc*., No. 3-20-cv-00343, and *Valeant Pharmaceuticals North America LLC v. Zydus Pharms. (USA) Inc.,* No. 2-18-cv-13635.

17. Zydus Lifesciences Limited is subject to personal jurisdiction in New Jersey because, among other things, Zydus Lifesciences Limited itself and through its wholly owned indirect subsidiaries Zydus Worldwide DMCC and Zydus Pharmaceuticals (USA) Inc. has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Lifesciences itself, and through its wholly owned indirect subsidiaries Zydus Worldwide DMCC and Zydus Pharmaceuticals (USA) Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within the New Jersey, and/or has engaged in systematic and continuous business contacts within the New Jersey. In addition, Zydus Lifesciences Limited is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC, and therefore the activities of Zydus Pharmaceuticals (USA) Inc. and Zydus Worldwide DMCC in this jurisdiction are attributed to Zydus Lifesciences Limited. On information and belief, Zydus Lifesciences Limited consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Valeant Pharmaceuticals North America LLC v. Zydus*

Pharms. (USA) Inc., No. 2-18-cv-13635, *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc*., No. 3-18-cv-11792, and *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc*., No. 3-18-cv-01994.

18. Upon information and belief, if Zydus's ANDA is approved, Zydus will directly or indirectly manufacture, market, sell, and/or distribute the ANDA Product within the United States, including in New Jersey, consistent with Zydus's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Zydus regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. Upon information and belief, Zydus's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, the ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the patents-in-suit in the event that the ANDA Product is approved before the patents-in-suit expire.

19. In the alternative, this Court has personal jurisdiction over Zydus Worldwide DMCC and Zydus Lifesciences Limited under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Salix's claims arise under federal law; (b) Zydus Worldwide DMCC and Zydus Lifesciences Limited are each a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Zydus Worldwide and Zydus Lifesciences Limited each has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus

Worldwide and Zydus Lifesciences Limited satisfies due process, and is consistent with the Constitution and laws of the United States.

20. Venue is proper in this district as to Zydus Lifesciences Limited pursuant to 28 U.S.C. § 1391 because, amongst other things, Zydus Lifesciences Limited is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

21. Venue is proper in this district as to Zydus Worldwide DMCC pursuant to 28 U.S.C. § 1391 because, amongst other things, Zydus Worldwide DMCC is a corporation organized and existing under the laws of the United Arab Emirates and is subject to personal jurisdiction in this judicial district.

22. Venue is proper in this district as to Zydus Pharmaceuticals (USA) Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, amongst other things, Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of New Jersey and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

23. Salix holds New Drug Application No. 020610 for balsalazide disodium, 750 mg capsules, which is marketed, prescribed, and sold as COLAZAL®.

24. COLAZAL® is indicated for the treatment of mildly to moderately active ulcerative colitis in patients 5 years of age and older.

25. On November 18, 2008, the ’872 patent, titled “Formulations and Uses of 2-hydroxy-5-phenylazobenzoic Acid Derivatives,” was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the ’872 patent is attached hereto as Exhibit A.

26. On December 1, 2009, the ’884 patent, titled “Formulations and Uses of 2-hydroxy-5-phenylazobenzoic Acid Derivatives,” was duly and legally issued to Salix Pharmaceuticals Ltd. as assignee. A true and correct copy of the ’884 patent is attached hereto as Exhibit B.

27. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the ’872 patent and ’884 patent are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the “Orange Book”) for COLAZAL®.

28. On July 30, 2013, the ’256 patent, titled “Formulations and Uses of 2-hydroxy-5-phenylazobenzoic Acid Derivatives,” was duly and legally issued to Salix Pharmaceuticals, Ltd. as the assignee. A true and correct copy of the ’256 patent is attached hereto as Exhibit C.

29. The Notice Letter does not allege non-infringement of certain claims of the ‘872 patent and the ’884 patent.

30. By not identifying non-infringement defenses for certain claims of the ’872 patent and the ’884 patent in the Notice Letter, Zydus admits the ANDA Product meets all limitations of those claims.

31. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claims of the ’872 patent or the ’884 patent.

32. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the ’872 patent and the ’884 patent in the Notice Letter, Zydus admitted the claims of the ’872 patent and the ’884 patent are valid under 35 U.S.C. §§ 101, 102 and 112, and are enforceable.

33. Salix is commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I
(Infringement of the '872 Patent)

34. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

35. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the claims of the '872 patent, including at least claim 1, by submitting or causing to be submitted to the FDA, Zydus's ANDA seeking approval to manufacture, use, import, offer to sell or sell the ANDA Product before the expiration of the '872 patent.

36. Upon information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Product immediately upon approval of its ANDA.

37. Upon information and belief, the manufacture, use, import, offer to sell, or sale of the ANDA Product will directly infringe the claims of the '872 patent, including at least claim 1.

38. Upon information and belief, the use of the ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '872 patent. Upon information and belief, Zydus specifically intends the ANDA Product to be used in a manner that infringes the claims of the '872 patent, including at least claim 1.

39. Upon information and belief, upon approval, Zydus will take active steps to encourage the use of the ANDA Product by physicians and/or patients with the knowledge and intent that the ANDA Product will be used by physicians and/or patients in a manner that infringes the claims of the '872 patent, including at least claim 1, for the pecuniary benefit of Zydus.

40. Upon information and belief, Zydus will induce infringement of claim 1 of the '872 patent by actively inducing the use of the ANDA Product to practice a method of increasing

the bioavailability of balsalazide and metabolites 5-aminosalicylic acid (5-ASA) and N-acetyl-5-ASA (NASA), said method comprising administering a therapeutically effective amount of a solid dosage form of balsalazide with food, wherein the solid dosage form is a tablet or capsule, wherein administering with food comprises administering the solid dosage form within 15 minutes after eating a meal, wherein the bioavailability of balsalazide, 5-ASA or NASA is increased compared to administering balsalazide without food, and wherein the method decreases the systemic adsorption of the 5-ASA and NASA metabolites.

41. Upon information and belief, Zydus knows that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '872 patent, that the ANDA Product is not a staple article or commodity of commerce, and that the ANDA Product and its proposed label are not suitable for substantial non-infringing use. Upon information and belief, Zydus will thus contribute to the infringement of the claims of the '872 patent, including at least claim 1.

42. Salix will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

COUNT II
(Infringement of the '884 Patent)

43. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

44. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the claims of the '884 patent, including at least claim 1, by submitting or causing to be submitted to the FDA, Zydus's ANDA seeking approval to manufacture, use, import, offer to sell or sell the ANDA Product before the expiration of the '884 patent.

45. Upon information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Product immediately upon approval of its ANDA.

46. Upon information and belief, the manufacture, use, import, offer to sell, or sale of the ANDA Product will directly infringe the claims of the '884 patent, including at least claim 1.

47. Upon information and belief, the use of the ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '884 patent. Upon information and belief, Zydus specifically intends the ANDA Product to be used in a manner that infringes the claims of the '884 patent, including at least claim 1.

48. Upon information and belief, upon approval, Zydus will take active steps to encourage the use of the ANDA Product by physicians and/or patients with the knowledge and intent that the ANDA Product will be used by physicians and/or patients in a manner that infringes the claims of the '884 patent, including at least claim 1, for the pecuniary benefit of Zydus.

49. Upon information and belief, Zydus will induce infringement of claim 1 of the '884 patent by actively inducing the use of the ANDA Product to practice a method of treating a gastrointestinal disorder, said method comprising administering a therapeutically effective amount of balsalazide with food, wherein administering with food comprises administering the solid dosage form within 15 minutes after eating a meal, and wherein the administration results in an increase in the bioavailability of balsalazide and its metabolites 5-aminosalicylic acid (5-ASA) and N-acetyl-5-ASA (NASA) to the colon as compared to administering balsalazide without food.

50. Upon information and belief, Zydus knows that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '884 patent, that the ANDA Product is not a staple article or commodity of commerce, and that the ANDA Product and its proposed label are not suitable for substantial non-infringing use. Upon information and belief, Zydus will thus contribute to the infringement of the claims of the '884 patent, including at least claim 1.

51. Salix will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

COUNT III
(Infringement of the '256 Patent)

52. Salix incorporates the allegations in the preceding paragraphs as if fully set forth herein.

53. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the claims of the '256 patent, including at least claim 1, by submitting or causing to be submitted to the FDA, Zydus's ANDA seeking approval to manufacture, use, import, offer to sell or sell the ANDA Product before the expiration of the '256 patent.

54. Upon information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Product immediately upon approval of its ANDA.

55. Upon information and belief, the manufacture, use, import, offer to sell, or sale of the ANDA Product will directly infringe the claims of the '256 patent, including at least claim 10.

56. Upon information and belief, the use of the ANDA Product in accordance with and as directed by its proposed product labeling will infringe one or more claims of the '256

patent. Upon information and belief, Zydus specifically intends the ANDA Product to be used in a manner that infringes the claims of the '256 patent, including at least claim 10.

57. Upon information and belief, upon approval, Zydus will take active steps to encourage the use of the ANDA Product by physicians and/or patients with the knowledge and intent that the ANDA Product will be used by physicians and/or patients in a manner that infringes the claims of the '256 patent, including at least claim 10, for the pecuniary benefit of Zydus.

58. Upon information and belief, Zydus will induce infringement of claim 10 of the '256 patent by actively inducing the use of the ANDA Product to practice a method for treating a gastrointestinal disorder in a male subject, wherein the gastrointestinal disorder comprises mild to moderately active ulcerative colitis, said method comprising administering to the male subject in need of treatment a therapeutically effective amount of balsalazide.

59. Upon information and belief, Zydus knows that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '256 patent, that the ANDA Product is not a staple article or commodity of commerce, and that the ANDA Product and its proposed label are not suitable for substantial non-infringing use. Upon information and belief, Zydus will thus contribute to the infringement of the claims of the '256 patent, including at least claim 10.

60. Salix will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Salix does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Salix requests the following relief:

i. A judgment that the patents-in-suit have been infringed under 35 U.S.C. § 271(e)(2) by Zydus's submission of Zydus's ANDA to the FDA;

ii. A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of the ANDA Product, or any other drug product the use of which infringes the patents-in-suit, be not earlier than the expiration dates of said patents, inclusive of any extension or additional period of exclusivity pursuant to 35 U.S.C. § 271(e)(4)(A);

iii. A preliminary and permanent injunction enjoining Zydus, and all persons acting in concert with Zydus, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product, or any other drug product whose use is covered by the patents-in-suit, prior to the expiration of said patents, inclusive of any extension or additional period of exclusivity;

iv. A judgement that the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product, or any other drug product whose use is covered by the patents-in-suit, prior to the expiration of said patents, will infringe and induce infringement of said patents;

v. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

vi. Costs and expenses in this action; and

vii. Such further and other relief as this Court may deem just and proper.

Dated: September 16, 2022

Respectfully submitted,

By: */s/ Harvey Bartle IV*
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