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

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A. and BAUSCH HEALTH IRELAND LTD., Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC. and ZYDUS LIFESCIENCES LIMITED, Defendants.	Case No.: 1:24-cv-9512 **COMPLAINT** *Document Filed Electronically*

Plaintiffs Salix Pharmaceuticals, Inc.; Salix Pharmaceuticals, Ltd.; Alfasigma, S.p.A.; and Bausch Health Ireland, Ltd. (collectively, "Salix"), by their attorneys, Morgan, Lewis & Bockius

LLP, file this Complaint for patent infringement against Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Zydus" or "Defendants") 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 Xifaxan® (rifaximin tablets, 550 mg) prior to the expiration of U.S. Patent Nos. 11,779,571 ("the '571 patent"), 11,564,912 ("the '912 patent"), 8,193,196 ("the '196 patent"), 8,518,949 ("the '949 patent"), 8,741,904 ("the '904 patent"), 9,271,968 ("the '968 patent"), and 10,703,763 ("the '763 patent") (collectively, the "Xifaxan® patents" or "patents-in-suit").

2. By letter dated August 15, 2024 ("Notice Letter"), Zydus Pharmaceuticals (USA) Inc., notified Salix that it had submitted to FDA ANDA No. 218650 ("Zydus's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, and/or sale of generic rifaximin 550 mg tablets (the "ANDA Product") under 21 U.S.C. § 355(j) prior to the expiration of the Xifaxan® patents. The Notice Letter stated that Zydus has received a Paragraph IV acceptance acknowledgement receipt letter from FDA. Brij Khera, Ph.D., Executive Vice President and Chief Legal Officer for Zydus Pharmaceuticals (USA) Inc., signed the Notice Letter. On information and belief, Zydus Pharmaceuticals (USA) submitted Zydus's ANDA to FDA from its office in Pennington, New Jersey and therefore infringed the Xifaxan® patents in New Jersey.

PARTIES

3. 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.

4. 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.

5. Plaintiff Alfasigma S.p.A. is a corporation organized and existing under the laws of Italy having a principal place of business at Via Ragazzi del '99, 5, 40133 Bologna, Italy.

6. Plaintiff Bausch Health Ireland Ltd. is a company organized and existing under the laws of Ireland having an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, D24 PPT3, Ireland.

7. On 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. On 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. On information and belief, Zydus Pharmaceuticals (USA) submitted Zydus's ANDA to FDA from its office in Pennington, New Jersey and therefore infringed the Xifaxan® patents in New Jersey.

8. On information and belief, 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. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, Gujarat,

India. On 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.

9. On information and belief, Zydus Pharmaceuticals (USA) Inc. is a wholly owned subsidiary of Zydus Lifesciences Limited.

10. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited acted in concert to prepare and submit Zydus' ANDA to FDA. On information and belief, Zydus Lifesciences Limited assisted with the preparation of Zydus's ANDA.

11. On information and belief, if Zydus's ANDA were approved, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited will directly or indirectly market, sell, and distribute the ANDA Product throughout the United States, including in New Jersey. On information and belief, Zydus Pharmaceuticals (USA) Inc. 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 intercompany agreements with each other. On information and belief, Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited participated in, assisted, and cooperated with each other in the acts complained of herein.

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

JURISDICTION AND VENUE

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

14. 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. On 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.

15. Zydus Lifesciences Limited is subject to personal jurisdiction in New Jersey because, among other things, Zydus Lifesciences Limited itself and through its wholly owned subsidiary 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. On information and belief, Zydus Lifesciences itself, and through its wholly owned subsidiary 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, on information and belief, it controls Zydus Pharmaceuticals (USA) Inc., and therefore the activities of Zydus Pharmaceuticals (USA) Inc. 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 (D.N.J. Sept. 6, 2018), *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc*., No. 3:18-cv-11792 (D.N.J. July 18, 2018), *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc*., No. 3:18-cv-01994 (D.N.J. Feb. 12, 2018) and *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, No. 2:22-cv-02964 (D.N.J. May 20, 2022).

16. On 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. On 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. On information and belief, Zydus's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. On 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.

17. In the alternative, this Court has personal jurisdiction over Zydus Lifesciences Limited under Federal Rule of Civil Procedure 4(k)(2)(A) because: (a) Salix's claims arise under federal law; (b) Zydus Lifesciences Limited is a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Zydus Lifesciences Limited 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 Lifesciences Limited satisfies due process, and is consistent with the Constitution and laws of the United States

18. 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.

19. 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. On information and belief, Zydus Lifesciences Limited consented to venue, did not contest venue, 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 (D.N.J. Sept. 6, 2018), *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc*., No. 3:18-cv-11792 (D.N.J. July 18, 2018), *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc*., No. 3:18-cv-01994 (D.N.J. Feb. 12, 2018) and *Aragon Pharms., Inc. v. Zydus Worldwide DMCC*, No. 2:22-cv-02964 (D.N.J. May 20, 2022).

THE XIFAXAN® NDA

20. Salix Pharmaceuticals, Inc. holds the approved New Drug Application ("NDA") Nos. 021361 and 022554 (a supplement to NDA No. 021361 that was granted a new NDA number for Xifaxan® (rifaximin) 550 mg tablets).

21. FDA approved NDA No. 021361 for Xifaxan® 200 mg tablets on May 25, 2004 and approved NDA No. 022554 for Xifaxan® 550 mg tablets on March 24, 2010. Xifaxan® 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy recurrence in adults and the treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults.

THE PATENTS-IN-SUIT

22. On October 10, 2023, the '571 patent, titled "Methods for Treating Irritable Bowel Syndrome (IBS)," was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the '571 patent is attached hereto as Exhibit A.

23. On January 31, 2023, the '912 patent, titled "Methods for Treating Irritable Bowel Syndrome (IBS)," was duly and legally issued to Salix Pharmaceuticals, Inc. as assignee. A true and correct copy of the '912 patent is attached hereto as Exhibit B.

24. On June 5, 2012, the '196 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfa Wassermann, S.p.A. as assignee. AlfaSigma, S.p.A. is the successor to Alfa Wasserman, S.p.A. by operation of law. A true and correct copy of the '196 patent is attached hereto as Exhibit C.

25. On August 27, 2013, the '949 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfa Wasserman S.p.A. as assignee. AlfaSigma, S.p.A. is the successor to Alfa Wasserman, S.p.A. by operation of law. A true and correct copy of the '949 patent is attached hereto as Exhibit D.

26. On June 3, 2014, the '904 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally

issued to Alfa Wasserman S.p.A. as assignee. AlfaSigma, S.p.A. is the successor to Alfa Wasserman, S.p.A. by operation of law. A true and correct copy of the '904 patent is attached hereto as Exhibit E.

27. On March 1, 2016, the '968 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to Alfa Wasserman S.p.A. as assignee. AlfaSigma, S.p.A. is the successor to Alfa Wasserman, S.p.A. by operation of law. A true and correct copy of the '968 patent is attached hereto as Exhibit F.

28. On July 7, 2020, the '763 patent, titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use thereof in the Medicinal Preparations," was duly and legally issued to AlfaSigma S.p.A. as assignee. A true and correct copy of the '763 patent is attached hereto as Exhibit G.

29. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xifaxan®.

30. Pursuant to agreements entered into between Bausch Health Ireland Ltd., Salix Pharmaceuticals, Inc., and Alfasigma S.p.A., Bausch Health Ireland Ltd. and Salix Pharmaceuticals, Inc. have substantial rights in the '196, '949, '904, '968, and '763 patents, including, but not limited to, an exclusive license to those patents in the United States and the right to sue for infringement of those patents in the United States. Pursuant to those agreements, Salix Pharmaceuticals, Inc. is the sole distributor in the United States of Xifaxan® tablets.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

31. On information and belief, Zydus submitted ANDA No. 218650 to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, and sale of Zydus's ANDA Product as a generic version of Xifaxan® 550 mg tablets.

32. On information and belief, Zydus's ANDA seeks FDA approval of Zydus's ANDA Product for the indication of the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

33. 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 several Xifaxan® patents, including the '571 patent, the '912 patent, the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent and that, in Zydus's opinion, certain claims of the Xifaxan® patents are invalid, unenforceable, and/or not infringed.

34. The Notice Letter does not allege non-infringement of the claims of the '571 patent, the '912 patent and the '968 patent.

35. By not identifying non-infringement defenses for the claims of the '571 patent, the '912 patent and the '968 patent in the Notice Letter, Zydus admits the ANDA Product meets all limitations of those claims.

36. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability of any claims of the '571 patent or the '912 patent.

37. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability defenses for the '571 patent and the '912 patent in the Notice Letter, Zydus

admitted the claims of the ’571 patent and the ’912 patent are valid under 35 U.S.C. §§ 101, 102 and 112, and are enforceable.

38. The Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102 or 103, or unenforceability of any claims of the ’196 patent, the ’949 patent, the ’904 patent and the ’968 patent.

39. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102 or 103, or unenforceability defenses for the ’196 patent, the ’949 patent, the ’904 patent and the ’968 patent in the Notice Letter, Zydus admitted the claims of the ’196 patent, the ’949 patent, the ’904 patent and the ’968 patent are valid under 35 U.S.C. §§ 101, 102 and 103, and are enforceable.

40. The Notice Letter does not allege invalidity or unenforceability of any claims of the ’763 patent.

41. By not identifying invalidity defenses or unenforceability defenses for the ’763 patent in the Notice Letter, Zydus admitted the claims of the ’763 patent are valid and enforceable.

42. On information and belief, Zydus’s statements of the factual and legal bases for its assertions regarding non-infringement and invalidity of the Xifaxan® patents are devoid of an objective good faith basis in either facts or the law. This case is exceptional.

43. An actual, real, immediate, and justiciable controversy exists between Salix and Zydus regarding the infringement, validity, and enforceability of the Xifaxan® patents.

44. 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 ’571 Patent)

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

46. By submitting the Zydus ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '571 patent, Zydus committed an act of infringement of the '571 patent under 35 U.S.C. § 271(e)(2)(A).

47. The '571 patent claims, *inter alia*, methods of treating diarrhea-associated irritable bowel syndrome with rifaximin.

48. Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to the expiration of the '571 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '571 patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

49. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '571 patent.

50. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

51. On information and belief, Zydus will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '571 patent.

52. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '571 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

53. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '571 patent's expiry will induce the direct infringement of one or more claims of the '571 patent.

54. On information and belief, Zydus's acts will be performed with knowledge of the '571 patent and with intent to encourage infringement prior to the '571 patent's expiry.

55. Zydus was aware of the existence of the '571 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '571 patent in the Notice Letter.

56. Salix will be substantially and 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 '912 Patent)

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

58. By submitting the Zydus ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '912 patent, Zydus committed an act of infringement of the '912 patent under 35 U.S.C. § 271(e)(2)(A).

59. The '912 patent claims, *inter alia*, methods of treating diarrhea-associated irritable bowel syndrome with rifaximin.

60. Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to the expiration of the '912 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '912 patent under 35 U.S.C. §§ 271(b) and/or (c), either literally or under the doctrine of equivalents.

61. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '912 patent.

62. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

63. On information and belief, Zydus will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '912 patent.

64. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '912 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

65. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '912 patent's expiry will induce the direct infringement of one or more claims of the '912 patent.

66. On information and belief, Zydus's acts will be performed with knowledge of the '912 patent and with intent to encourage infringement prior to the '912 patent's expiry.

67. Zydus was aware of the existence of the '912 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '912 patent in the Notice Letter.

68. Salix will be substantially and 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 '196 Patent)

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

70. By submitting the Zydus ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '196 patent, Zydus committed an act of infringement of the '196 patent under 35 U.S.C. § 271(e)(2)(A).

71. The '196 patent claims, *inter alia*, a composition comprising a polymorphic form of rifaximin and methods of treating bacterial activity in the gastrointestinal tract using a composition comprising a polymorphic form of rifaximin.

72. On information and belief, Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to the expiration of the '196 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '196 patent under 35 U.S.C. §§ 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

73. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '196 patent.

74. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

75. On information and belief, Zydus will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '196 patent.

76. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '196 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

77. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '196 patent's expiry will induce the direct infringement of one or more claims of the '196 patent.

78. On information and belief, Zydus's acts will be performed with knowledge of the '196 patent and with intent to encourage infringement prior to the '196 patent's expiry.

79. Zydus was aware of the existence of the '196 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '196 patent in the Notice Letter.

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

COUNT IV
(Infringement of the '949 Patent)

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

82. By submitting the Zydus ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '949 patent, Zydus committed an act of infringement of the '949 patent under 35 U.S.C. § 271(e)(2)(A).

83. The ’949 patent claims, *inter alia*, a composition comprising a polymorphic form of rifaximin.

84. On information and belief, Zydus’s manufacture, use, sale, offer for sale, or importation into the United States of Zydus’s ANDA Product prior to the expiration of the ’949 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’949 patent under 35 U.S.C. §§ 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

85. On information and belief, Zydus’s ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the ’949 patent.

86. On information and belief, these directly infringing uses will occur with Zydus’s specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

87. On information and belief, Zydus will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix’s rights under the ’949 patent.

88. On information and belief, Zydus knows or should know Zydus’s ANDA product will be especially made or especially adapted for use in infringing the ’949 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

89. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus’s ANDA Product prior to the ’949 patent’s expiry will induce the direct infringement of one or more claims of the ’949 patent.

90. On information and belief, Zydus's acts will be performed with knowledge of the '949 patent and with intent to encourage infringement prior to the '949 patent's expiry.

91. Zydus was aware of the existence of the '949 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '949 patent in the Notice Letter.

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

COUNT V
(Infringement of the '904 Patent)

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

94. By submitting the Zydus ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '904 patent, Zydus committed an act of infringement of the '904 patent under 35 U.S.C. § 271(e)(2)(A).

95. The '904 patent claims, *inter alia*, a polymorphic form of rifaximin and methods of treating bacterial activity in the gastrointestinal tract using a composition comprising a polymorphic form of rifaximin.

96. On information and belief, Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to the expiration of the '904 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '904 patent under 35 U.S.C. §§ 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

97. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '904 patent.

98. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

99. On information and belief, Zydus will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '904 patent.

100. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '904 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

101. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '904 patent's expiry will induce the direct infringement of one or more claims of the '904 patent.

102. On information and belief, Zydus's acts will be performed with knowledge of the '904 patent and with intent to encourage infringement prior to the '904 patent's expiry.

103. Zydus was aware of the existence of the '904 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '904 patent in the Notice Letter.

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

COUNT VI
(Infringement of the '968 Patent)

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

106. By submitting the Zydus ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '968 patent, Zydus committed an act of infringement of the '968 patent under 35 U.S.C. § 271(e)(2)(A).

107. The '968 patent claims, *inter alia*, a composition comprising rifaximin.

108. On information and belief, Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product prior to the expiration of the '968 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '968 patent under 35 U.S.C. §§ 271(a), (b) and/or (c), either literally or under the doctrine of equivalents.

109. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '968 patent.

110. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

111. On information and belief, Zydus will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '968 patent.

112. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '968 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

113. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '968 patent's expiry will induce the direct infringement of one or more claims of the '968 patent.

114. On information and belief, Zydus's acts will be performed with knowledge of the '968 patent and with intent to encourage infringement prior to the '968 patent's expiry.

115. Zydus was aware of the existence of the '968 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '968 patent in the Notice Letter.

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

COUNT VII
(Infringement of the '763 Patent)

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

118. By submitting the Zydus ANDA to FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '763 patent, Zydus committed an act of infringement of the '763 patent under 35 U.S.C. § 271(e)(2)(A).

119. The '763 patent claims, *inter alia*, methods of treating bacterial activity in the gastrointestinal tract using a composition comprising a polymorphic form of rifaximin.

120. On information and belief, Zydus's manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product (which is an antibacterial drug) prior to the expiration of the '763 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '763 patent under 35 U.S.C. §§ 271 (b) and/or (c), either literally or under the doctrine of equivalents.

121. On information and belief, Zydus's ANDA Product, if approved by FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of one or more claims of the '763 patent.

122. On information and belief, these directly infringing uses will occur with Zydus's specific intent and encouragement, and will be uses that Zydus knows or should know will occur.

123. On information and belief, Zydus will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Salix's rights under the '763 patent.

124. On information and belief, Zydus knows or should know Zydus's ANDA product will be especially made or especially adapted for use in infringing the '763 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

125. On information and belief, Zydus knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Product prior to the '763 patent's expiry will induce the direct infringement of one or more claims of the '763 patent.

126. On information and belief, Zydus's acts will be performed with knowledge of the '763 patent and with intent to encourage infringement prior to the '763 patent's expiry.

127. Zydus was aware of the existence of the '763 patent and its listing in the Orange Book as demonstrated by Zydus's reference to the '763 patent in the Notice Letter.

128. Salix will be substantially and 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. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 218650 under Section 505(j) of the Federal Food, Drug and Cosmetic Act

(21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of any of the patents in suit, inclusive of any extension or additional period of exclusivity;

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

vii. Costs and expenses in this action; and

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

Dated: September 27, 2024

Respectfully submitted,

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