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*Attorneys for Plaintiffs Salix Pharmaceuticals, Inc.,  
Salix Pharmaceuticals, Ltd., Alfasigma S.p.A., and  
Bausch Health Ireland Ltd.*

**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.

AMNEAL PHARMACEUTICALS OF NEW  
YORK, LLC, and AMNEAL EU, LIMITED,

Defendants.

Case No.: 1:24-cv-04607

**FIRST AMENDED 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 First Amended Complaint for patent infringement against Amneal Pharmaceuticals of New York, LLC, and Amneal EU, Limited (collectively, “Amneal” or “Defendants”) and hereby allege as follows:

**PARTIES**

1. 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.

2. 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.

3. 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.

4. 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.

5. On information and belief, defendant Amneal Pharmaceuticals of New York, LLC is a limited liability company organized and existing under the laws of Delaware with its principal place of business at 50 Horseblock Road, Brookhaven, New York 11719 and is the U.S. agent for Amneal EU, Limited, including with respect to ANDA No. 218862. In its letter dated February 27, 2024 (“Notice Letter”), Amneal stated that Amneal Pharmaceuticals of New York, LLC’s address is 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807. On information and belief, Amneal Pharmaceuticals of New York, LLC is a wholly-owned subsidiary of Amneal Pharmaceuticals, LLC. Upon further information and belief, Amneal Pharmaceuticals of New

York, LLC is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

6. On information and belief, defendant Amneal EU, Limited is a corporation organized and existing under the laws of Ireland with its principal place of business at Cahir Road, Cashel, Co. Tipperary, E25 XD51, Ireland and is indirectly wholly owned by Amneal Pharmaceuticals, Inc. Upon further information and belief, Amneal EU, Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various related companies, including Amneal Pharmaceuticals of New York, LLC.<sup>1</sup>

7. On information and belief, Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited are both subsidiaries of Amneal Pharmaceuticals, Inc..

8. On information and belief, Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited acted in concert to prepare and submit Amneal's ANDA to FDA.

9. On information and belief, if Amneal's ANDA were approved, Amneal EU, Limited and Amneal Pharmaceuticals of New York, LLC would directly or indirectly market, sell, and distribute the ANDA Product throughout the United States, including in New Jersey. On information and belief, Amneal Pharmaceuticals of New York, LLC and Amneal EU, 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.

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<sup>1</sup> Plaintiffs have agreed to exclude Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Private Limited and Amneal Pharmaceuticals, Inc., as defendants in this First Amended Complaint and, in turn, defendants have agreed that those entities will be bound by any judgment or order issued in this case, including appeals, and to provide discovery as if they were named defendants.

On information and belief, Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited participated in, assisted, and cooperated with each other in the acts complained of herein.

10. On information and belief, following any FDA approval of Amneal's ANDA, Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited will act in concert to distribute and sell the ANDA Product throughout the United States, including within New Jersey.

### **JURISDICTION AND VENUE**

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

12. Amneal Pharmaceuticals of New York, LLC 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. Amneal Pharmaceuticals of New York, LLC has a place of business in New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. In particular, in its Notice Letter, Amneal Pharmaceuticals of New York, LLC listed its address as 400 Crossing Boulevard, Bridgewater, New Jersey 08807 and indicated that notice should be sent to its agent at that address. It therefore has consented to general jurisdiction in New Jersey. On information and belief, Amneal Pharmaceuticals of New York, LLC 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.

13. On information and belief, Amneal Pharmaceuticals of New York, LLC consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in the District of New Jersey

in one or more prior litigations, including: *Teva Branded Pharmaceutical Products, R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC*, No. 2:23-cv-20964 (D.N.J. Oct. 6, 2023); *Celgene Corp. v. Amneal Pharmaceuticals of New York, LLC*, No. 2:24-cv-00500 (D.N.J. Jan. 26, 2024); *Janssen Products, L.P. v. Amneal Pharmaceuticals, LLC*, No. 2:18-cv-17585 (D.N.J. Dec. 26, 2018); *BTG International Ltd. v. Actavis Labs. FL, Inc.*, No. 2:15-cv-05909 (D.N.J. July 31, 2015); and *THERAPEUTICSMD, Inc. v. Amneal Pharmaceuticals, Inc.*, No. 3:20-cv-05256 (D.N.J. Apr. 29, 2020).

14. Amneal EU, Limited 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. Amneal EU, Limited has conducted and continues to conduct business in this judicial district and maintains extensive and systematic contacts with New Jersey, including through the marketing, distribution and/or sale of generic pharmaceutical drugs in New Jersey, either directly or through its affiliates, agents and/or alter egos, including Amneal Pharmaceuticals of New York, LLC, including by selling pharmaceutical products in New Jersey. In particular, in the Notice Letter, Amneal Pharmaceuticals of New York, LLC indicated it was the U.S. agent for Amneal EU, Limited and listed its address as 400 Crossing Boulevard, Bridgewater, New Jersey 08807 and indicated that notice should be sent to its agent at that address.

15. On information and belief, Amneal EU, Limited consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in the District of New Jersey in one or more prior litigations, including: *Celgene Corp. v. Amneal Pharmaceuticals of New York, LLC*, No. 2:24-cv-00500 (D.N.J. Jan. 26, 2024).

16. On information and belief, if Amneal's ANDA were approved, Amneal would directly or indirectly manufacture, market, sell, and/or distribute the ANDA Product within the United States, including in New Jersey, consistent with Amneal's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Amneal 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, Amneal'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 would 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 were approved before the patents-in-suit expire.

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

18. Venue is proper in this District as to Amneal Pharmaceuticals of New York, LLC pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, among other things, it (a) has a principal place

of business in New Jersey; (b) has acted in concert with Amneal EU, Limited to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (c) has engaged in regular and established business contacts with New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities; and (d) has made agreements with retailers, wholesalers or distributors providing for the distribution of Defendants' products in New Jersey.

19. On information and belief, Amneal Pharmaceuticals of New York, LLC consented to venue, did not contest venue, or asserted counterclaims in the District of New Jersey in one or more prior litigations, including: *Teva Branded Pharmaceutical Products, R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC*, No. 2:23-cv-20964 (D.N.J. Oct. 6, 2023); *Celgene Corp. v. Amneal Pharmaceuticals of New York, LLC*, No. 2:24-cv-00500 (D.N.J. Jan. 26, 2024); *Janssen Products, L.P. v. Amneal Pharmaceuticals, LLC*, No. 2:18-cv-17585 (D.N.J. Dec. 26, 2018); *BTG International Ltd. v. Actavis Labs. FL, Inc.*, No. 2:15-cv-05909 (D.N.J. July 31, 2015); and *THERAPEUTICSMD, Inc. v. Amneal Pharmaceuticals, Inc.*, No. 3:20-cv-05256 (D.N.J. Apr. 29, 2020).

20. Venue is proper in this District as to Amneal EU, Limited pursuant to 28 U.S.C. § 1391 because, among other things, it (a) has acted in concert with Amneal Pharmaceuticals of New York, LLC to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (b) conducts business, individually and/or in concert with its U.S. agent, Amneal Pharmaceuticals of New York, LLC, that is located in New Jersey, in this District and (c) has engaged in regular and established business contacts with New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making,

shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities.

21. Venue also is proper in this District for Amneal EU, Limited because, among other things, it is a foreign corporation organized and existing under the laws of Ireland and is subject to personal jurisdiction in this judicial district. *See* 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

22. On information and belief, Amneal EU, Limited consented to venue, did not contest venue, or asserted counterclaims in the District of New Jersey in one or more prior litigations, including: *Celgene Corp. v. Amneal Pharmaceuticals of New York, LLC*, No. 2:24-cv-00500 (D.N.J. Jan. 26, 2024).

### **NATURE OF THE ACTION**

23. 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 Amneal'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<sup>®</sup> (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<sup>®</sup> patents" or "patents-in-suit").



**THE XIFAXAN® NDA**

24. 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).

25. 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**

26. 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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®.

34. 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**

35. By letter dated February 27, 2024 (“Notice Letter”), Amneal Pharmaceuticals of New York, LLC, U.S. agent for Amneal EU, Limited, notified Salix that it had submitted to FDA ANDA No. 218862 (“Amneal’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 Amneal has received a Paragraph IV acceptance acknowledgement receipt letter from FDA. Bryan Sommese, Esq., Senior Patent Litigation Counsel – IP for Amneal Pharmaceuticals, Inc., signed the Notice Letter.

36. On information and belief, Amneal submitted ANDA No. 218862 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 Amneal’s ANDA Product as a generic version of Xifaxan® 550 mg tablets.

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

38. The Notice Letter stated that Amneal’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 Amneal's opinion, certain claims of the Xifaxan® patents are invalid, unenforceable, and/or not infringed.

39. On information and belief, Amneal'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.

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

41. 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)**

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

43. By submitting the Amneal 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 Amneal's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '571 patent, Amneal committed an act of infringement of the '571 patent under 35 U.S.C. § 271(e)(2)(A).

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

45. Amneal's manufacture, use, sale, offer for sale, or importation into the United States of Amneal'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.

46. On information and belief, Amneal'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.

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

48. On information and belief, Amneal 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.

49. On information and belief, Amneal knows or should know Amneal'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.

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

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

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

53. 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)**

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

55. By submitting the Amneal 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 Amneal's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '912 patent, Amneal committed an act of infringement of the '912 patent under 35 U.S.C. § 271(e)(2)(A).

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

57. Amneal's manufacture, use, sale, offer for sale, or importation into the United States of Amneal'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.

58. On information and belief, Amneal'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.

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

60. On information and belief, Amneal 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.

61. On information and belief, Amneal knows or should know Amneal'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.

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

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

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

65. 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)**

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

67. By submitting the Amneal 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 Amneal's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '196 patent, Amneal committed an act of infringement of the '196 patent under 35 U.S.C. § 271(e)(2)(A).

68. 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.

69. On information and belief, Amneal's manufacture, use, sale, offer for sale, or importation into the United States of Amneal'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.

70. On information and belief, Amneal'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.

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

72. On information and belief, Amneal 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.

73. On information and belief, Amneal knows or should know Amneal'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.

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

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



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

77. 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)**

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

79. By submitting the Amneal 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 Amneal's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '949 patent, Amneal committed an act of infringement of the '949 patent under 35 U.S.C. § 271(e)(2)(A).

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

81. On information and belief, Amneal's manufacture, use, sale, offer for sale, or importation into the United States of Amneal'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.

82. On information and belief, Amneal'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.

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

84. On information and belief, Amneal 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.

85. On information and belief, Amneal knows or should know Amneal'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.

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

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

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

89. 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)**

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

91. By submitting the Amneal 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 Amneal's ANDA Product throughout the United States, including New

Jersey, prior to the expiration of the '904 patent, Amneal committed an act of infringement of the '904 patent under 35 U.S.C. § 271(e)(2)(A).

92. 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.

93. On information and belief, Amneal's manufacture, use, sale, offer for sale, or importation into the United States of Amneal'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.

94. On information and belief, Amneal'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.

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

96. On information and belief, Amneal 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.

97. On information and belief, Amneal knows or should know Amneal'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.

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

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

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

101. 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)**

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

103. By submitting the Amneal 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 Amneal's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '968 patent, Amneal committed an act of infringement of the '968 patent under 35 U.S.C. § 271(e)(2)(A).

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

105. On information and belief, Amneal's manufacture, use, sale, offer for sale, or importation into the United States of Amneal'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.

106. On information and belief, Amneal'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.

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

108. On information and belief, Amneal 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.

109. On information and belief, Amneal knows or should know Amneal'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.

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

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

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

113. 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)**

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

115. By submitting the Amneal 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 Amneal's ANDA Product throughout the United States, including New Jersey, prior to the expiration of the '763 patent, Amneal committed an act of infringement of the '763 patent under 35 U.S.C. § 271(e)(2)(A).

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

117. On information and belief, Amneal's manufacture, use, sale, offer for sale, or importation into the United States of Amneal'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.

118. On information and belief, Amneal'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.

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

120. On information and belief, Amneal 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.

121. On information and belief, Amneal knows or should know Amneal'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.

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

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

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

125. 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 Amneal's submission of Amneal'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 Amneal, and all persons acting in concert with Amneal, 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. 218862 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: June 4, 2024

Respectfully submitted,

By: s/ Harvey Bartle IV

Harvey Bartle IV

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*Attorneys for Plaintiffs Salix Pharmaceuticals, Inc.,  
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Bausch Health Ireland Ltd.*

**CERTIFICATE OF SERVICE**

I, Harvey Bartle IV, do hereby certify that on June 4, 2024, I caused a true and correct copy of the foregoing Complaint to be served on all counsel of record via CM/ECF.

Dated: June 4, 2024

*s/ Harvey Bartle IV*  
Harvey Bartle IV