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UNITED STATES DISTRICT COURT
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.**	**Civil Action No. 3:24-cv-4607 (ESK)(AMD)** **(Filed Electronically)**

DEFENDANTS AMNEAL PHARMACEUTICALS OF NEW YORK, LLC AND AMNEAL EU, LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO THE FIRST AMENDED COMPLAINT

Defendants Amneal Pharmaceuticals of New York, LLC ("Amneal NY") and Amneal EU, Limited ("Amneal EU") (together, "Defendants" or "Amneal") respond to the allegations in the First Amended Complaint (Dkt. 23, "the FAC") by Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Alfasigma S.p.A., and Bausch Health Ireland, Ltd. (collectively, "Plaintiffs" or "Salix"). Amneal bases its responses on its knowledge as to its own activities, and on information and belief as to the activities of others. The numbered paragraphs below correspond to the numbered paragraphs in the FAC. To the extent that the section headings in the FAC contain allegations, those allegations are denied. If not specifically admitted, the allegations of the FAC are denied.

PARTIES

1. Amneal is without sufficient information to admit or deny the allegations in Paragraph 1 of the FAC, and therefore denies those allegations.

2. Amneal is without sufficient information to admit or deny the allegations in Paragraph 2 of the FAC, and therefore denies those allegations.

3. Amneal is without sufficient information to admit or deny the allegations in Paragraph 3 of the FAC, and therefore denies those allegations.

4. Amneal is without sufficient information to admit or deny the allegations in Paragraph 4 of the FAC, and therefore denies those allegations.

5. Admitted.

6. Admitted.

7. Admitted.

8. Amneal admits that Amneal NY, U.S. Agent for Amneal EU, filed Abbreviated New Drug Application ("ANDA") No. 218862 to obtain approval from the U.S. Food & Drug Administration ("FDA") to commercialize rifaximin tablets, 550 mg ("Amneal's ANDA product"). Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 11 of the FAC.

9. Denied.

10. Denied.

JURISDICTION AND VENUE

11. The allegations of this paragraph of the FAC contain conclusions of law for which no response is required.

12. Paragraph 12 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 12 of the FAC is required, for purposes of this Action only, Amneal does not contest personal jurisdiction in this Court, and Amneal admits that Amneal NY 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. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 12 of the FAC.

13. Paragraph 13 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 13 of the FAC is required, for purposes of this Action only, Amneal does not contest personal jurisdiction in this Court. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 13 of the FAC.

14. Paragraph 14 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 14 of the FAC is required, for purposes of this Action only, Amneal does not contest personal jurisdiction in this Court, and Amneal admits that

Amneal NY is the U.S. agent for Amneal EU. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 14 of the FAC.

15. Paragraph 15 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 15 of the FAC is required, for purposes of this Action only, Amneal does not contest personal jurisdiction in this Court. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 15 of the FAC.

16. Amneal admits that Amneal EU, through Amneal NY, filed ANDA No. 218862 to obtain approval from the FDA to market Amneal's ANDA product. The remaining allegations in Paragraph 16 of the FAC contain legal conclusions to which no answer is required. To the extent an answer to Paragraph 16 of the FAC is required, for purposes of this Action only, Amneal does not contest personal jurisdiction of Amneal in this Court. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 16 of the FAC.

17. Paragraph 17 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 17 of the FAC is required, for purposes of this Action only, Amneal does not contest personal jurisdiction in this Court. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 17 of the FAC.

18. Paragraph 18 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 18 of the FAC is required, for purposes of this Action only, Amneal does not contest venue, and Amneal admits that Amneal NY has a place of business in New Jersey. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 18 of the FAC.

19. Paragraph 19 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 19 of the FAC is required, for purposes of this

Action only, Amneal does not contest venue. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 19 of the FAC.

20. Paragraph 20 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 20 of the FAC is required, for purposes of this Action only, Amneal does not contest venue. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 20 of the FAC.

21. Paragraph 21 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 21 of the FAC is required, for purposes of this Action only, Amneal does not contest venue, and Amneal admits that Amneal EU is a foreign corporation organized and existing under the laws of Ireland. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 21 of the FAC.

22. Paragraph 22 of the FAC contains legal conclusions to which no answer is required. To the extent an answer to Paragraph 22 of the FAC is required, for purposes of this Action only, Amneal does not contest venue. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 22 of the FAC.

NATURE OF THE ACTION

23. Paragraph 23 of the FAC contains legal conclusion to which no answer is required. To the extent an answer to Paragraph 23 of the FAC is required, Amneal admits that the FAC purports to set forth claims of alleged infringement under the patent laws of the United States and the Declaratory Judgment Act. Amneal admits that this action purports to relate to Amneal's ANDA No. 218862, which seeks approval from the FDA to market Amneal ANDA product 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 "patents-in-suit"). Amneal denies any allegations of infringement of the patents-in-suit. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 23 of the FAC.

THE XIFAXAN® NDA

24. Admitted that the FDA's website lists Salix Pharmaceuticals, Inc. as the applicant for New Drug Application ("NDA") No. 021361 for rifaximin tablets, 550 mg, which it sells under the trade name Xifaxan®. Amneal is without information sufficient to admit or deny the remaining allegations in Paragraph 24 of the FAC and therefore denies those allegations.

25. Admitted that FDA's website indicates that FDA approved NDA No. 021361 for Xifaxan® 200 mg tablets on May 25, 2004, and that FDA approved an NDA for Xifaxan® 550 mg tablets on March 24, 2010. Amneal is without information sufficient to admit or deny the remaining allegations in Paragraph 25 of the FAC and therefore denies those allegations.

THE PATENTS-IN-SUIT

26. Amneal admits that, on its face, the '571 patent is titled "Methods for Treating Irritable Bowel Syndrome (IBS)," is assigned to Salix Pharmaceuticals, Inc., and was issued by the United States Patent & Trademark Office ("Patent Office") on October 10, 2023. Amneal admits that Exhibit A to the FAC appears to be a copy of the '571 patent. Amneal is without information sufficient to admit or deny the remaining allegations in Paragraph 26 of the FAC and therefore denies those allegations.

27. Amneal admits that, on its face, the '912 patent is titled "Methods for Treating Irritable Bowel Syndrome (IBS)," is assigned to Salix Pharmaceuticals, Inc., and was issued by the Patent Office on January 31, 2023. Amneal admits that Exhibit B to the FAC appears to be a

copy of the ’912 patent. Amneal is without information sufficient to admit or deny the remaining allegations in Paragraph 27 of the FAC and therefore denies those allegations.

28. Amneal admits that, on its face, the ’196 patent is titled “Polymorphous Forms of Rifaximin, Processes for their Production and Use Thereof in the Medicinal Preparations,” is assigned to Alfa Wassermann, S.p.A., and was issued by the Patent Office on June 5, 2012. Amneal admits that Exhibit C to the FAC appears to be a copy of the ’196 patent. Amneal is without information sufficient to admit or deny the remaining allegations in Paragraph 28 of the FAC and therefore denies those allegations.

29. Amneal admits that, on its face, the ’949 patent is titled “Polymorphous Forms of Rifaximin, Processes for their Production and Use Thereof in the Medicinal Preparations,” is assigned to ALFA Wassermann S.p.A., and was issued by the Patent Office on August 27, 2013. Amneal admits that Exhibit D to the FAC appears to be a copy of the ’949 patent. Amneal is without information sufficient to admit or deny the remaining allegations in Paragraph 29 of the FAC and therefore denies those allegations.

30. Amneal admits that, on its face, the ’904 patent is titled “Polymorphous Forms of Rifaximin, Processes for their Production and Use Thereof in the Medicinal Preparations,” is assigned to Alfa Wassermann S.P.A., and was issued by the Patent Office on June 3, 2014. Amneal admits that Exhibit E to the FAC appears to be a copy of the ’904 patent. Amneal is without information sufficient to admit or deny the remaining allegations in Paragraph 30 of the FAC and therefore denies those allegations.

31. Amneal admits that, on its face, the ’968 patent is titled “Polymorphous Forms of Rifaximin, Processes for their Production and Use Thereof in the Medicinal Preparations,” is assigned to Alfa Wassermann S.p.A., and was issued by the Patent Office on March 1, 2016.

Amneal admits that Exhibit F to the FAC appears to be a copy of the '968 patent. Amneal is without information sufficient to admit or deny the remaining allegations in Paragraph 31 of the FAC and therefore denies those allegations.

32. Amneal admits that, on its face, the '763 patent is titled "Polymorphous Forms of Rifaximin, Processes for their Production and Use Thereof in the Medicinal Preparations," is assigned to Alfasigma S.p.A., and was issued by the Patent Office on July 7, 2020. Amneal admits that Exhibit G to the FAC appears to be a copy of the '763 patent. Amneal is without information sufficient to admit or deny the remaining allegations in Paragraph 32 of the FAC and therefore denies those allegations.

33. Amneal admits that the patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Xifaxan®, 550 mg tablets. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 33 of the FAC.

34. Amneal is without information sufficient to admit or deny the allegations in Paragraph 34 of the FAC and therefore denies those allegations.

CLAIMS FOR RELIEF—PATENT INFRINGEMENT

35. Admitted.

36. Admitted.

37. Amneal admits that it submitted ANDA No. 218862 seeking approval to engage in the commercial manufacture, use, or sale of Amneal's ANDA product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 37 of the FAC.

38. Admitted.

39. Denied.

40. Paragraph 40 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal admits that there is an actual and substantial controversy between Salix and Amneal. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 40 of the FAC.

41. Paragraph 41 of the FAC contains legal conclusions to which no response is required. To the extent that a response is required, Amneal admits that the Complaint commencing this action was dated April 5, 2024. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 41 of the FAC.

COUNT I
([Alleged] Infringement of the '571 Patent)

42. Paragraph 42 of the FAC contains no allegations of fact to which a response is required. If an answer is required, Amneal incorporates its responses to Paragraphs 1 to 41 of the FAC as if fully set forth herein.

43. Paragraph 43 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal admits that Amneal NY, U.S. Agent for Amneal EU, filed ANDA No. 218862 to obtain approval from the FDA to commercialize Amneal's ANDA product. Amneal denies any allegations of infringement of the '571 patent. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 43 of the FAC.

44. Paragraph 44 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal states that the '571 patent speaks for itself and is the best source for its content, subject to the Court's claim construction. Amneal denies any remaining allegations in Paragraph 44 of the FAC.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

51. Denied.

52. Amneal admits that it was aware of the '571 patent and its listing in the FDA's "Orange Book" for Xifaxan®, 550 mg tablets on the date it sent the Amneal Notice Letter. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 52 of the FAC.

53. Denied.

COUNT II
([Alleged] Infringement of the '912 Patent)

54. Paragraph 54 of the FAC contains no allegations of fact to which a response is required. If an answer is required, Amneal incorporates its responses to Paragraphs 1 to 53 of the FAC as if fully set forth herein.

55. Paragraph 55 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal admits that Amneal NY, U.S. Agent for Amneal EU, filed ANDA No. 218862 to obtain approval from the FDA to commercialize Amneal's ANDA product. Amneal denies any allegations of infringement of the '912 patent. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 55 of the FAC.

56. Paragraph 56 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal states that the '912 patent speaks for

itself and is the best source for its content, subject to the Court's claim construction. Amneal denies any remaining allegations in Paragraph 56 of the FAC.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Amneal admits that it was aware of the '912 patent and its listing in the FDA's "Orange Book" for Xifaxan®, 550 mg tablets on the date it sent the Amneal Notice Letter. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 64 of the FAC.

65. Denied.

COUNT III
([Alleged] Infringement of the '196 Patent)

66. Paragraph 66 of the FAC contains no allegations of fact to which a response is required. If an answer is required, Amneal incorporates its responses to Paragraphs 1 to 65 of the FAC as if fully set forth herein.

67. Paragraph 67 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal admits that Amneal NY, U.S. Agent for Amneal EU, filed ANDA No. 218862 to obtain approval from the FDA to commercialize Amneal's ANDA product. Amneal denies any allegations of infringement of the '196 patent.

Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 67 of the FAC.

68. Paragraph 68 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal states that the '196 patent speaks for itself and is the best source for its content, subject to the Court's claim construction. Amneal denies any remaining allegations in Paragraph 68 of the FAC.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

76. Amneal admits that it was aware of the '196 patent and its listing in the FDA's "Orange Book" for Xifaxan®, 550 mg tablets on the date it sent the Amneal Notice Letter. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 76 of the FAC.

77. Denied.

COUNT IV
(Alleged] Infringement of the '949 Patent)

78. Paragraph 78 of the FAC contains no allegations of fact to which a response is required. If an answer is required, Amneal incorporates its responses to Paragraphs 1 to 77 of the FAC as if fully set forth herein.

79. Paragraph 79 states legal conclusions to which no response is required. To the extent that a response is required, Amneal admits that Amneal NY, U.S. Agent for Amneal EU, filed ANDA No. 218862 to obtain approval from the FDA to commercialize Amneal's ANDA product. Amneal denies any allegations of infringement of the '949 patent. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 79 of the FAC.

80. Paragraph 80 states legal conclusions to which no response is required. To the extent that a response is required, Amneal states that the '949 patent speaks for itself and is the best source for its content, subject to the Court's claim construction. Amneal denies any remaining allegations in Paragraph 80 of the FAC.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

87. Denied.

88. Amneal admits that it was aware of the '949 patent and its listing in the FDA's "Orange Book" for Xifaxan®, 550 mg tablets on the date it sent the Amneal Notice Letter. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 88 of the FAC.

89. Denied.

COUNT V
([Alleged] Infringement of the '904 Patent)

90. Paragraph 90 of the FAC contains no allegations of fact to which a response is required. If an answer is required, Amneal incorporates its responses to Paragraphs 1 to 89 of the FAC as if fully set forth herein.

91. Paragraph 91 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal admits that Amneal NY, U.S. Agent for Amneal EU, filed ANDA No. 218862 to obtain approval from the FDA to commercialize Amneal's ANDA product. Amneal denies any allegations of infringement of the '904 patent. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 91 of the FAC.

92. Paragraph 92 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal states that the '904 patent speaks for itself and is the best source for its content, subject to the Court's claim construction. Amneal denies any remaining allegations in Paragraph 92 of the FAC.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

97. Denied.

98. Denied.

99. Denied.

100. Amneal admits that it was aware of the '904 patent and its listing in the FDA's "Orange Book" for Xifaxan®, 550 mg tablets on the date it sent the Amneal Notice Letter.

Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 100 of the FAC.

101. Denied.

COUNT VI
([Alleged] Infringement of the '968 Patent)

102. Paragraph 102 of the FAC contains no allegations of fact to which a response is required. If an answer is required, Amneal incorporates its responses to Paragraphs 1 to 101 of the FAC as if fully set forth herein.

103. Paragraph 103 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal admits that Amneal NY, U.S. Agent for Amneal EU, filed ANDA No. 218862 to obtain approval from the FDA to commercialize Amneal's ANDA product. Amneal denies any allegations of infringement of the '968 patent. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 103 of the FAC.

104. Paragraph 104 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal states that the '968 patent speaks for itself and is the best source for its content, subject to the Court's claim construction. Amneal denies any remaining allegations in Paragraph 104 of the FAC.

105. Denied.

106. Denied.

107. Denied.

108. Denied.

109. Denied.

110. Denied.

111. Denied.

112. Amneal admits that it was aware of the '968 patent and its listing in the FDA's "Orange Book" for Xifaxan®, 550 mg tablets on the date it sent the Amneal Notice Letter. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 112 of the FAC.

113. Denied.

COUNT VII
([Alleged] Infringement of the '763 Patent)

114. Paragraph 114 of the FAC contains no allegations of fact to which a response is required. If an answer is required, Amneal incorporates its responses to Paragraphs 1 to 113 of the FAC as if fully set forth herein.

115. Paragraph 115 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal admits that Amneal NY, U.S. Agent for Amneal EU, filed ANDA No. 218862 to obtain approval from the FDA to commercialize Amneal's ANDA product. Amneal denies any allegations of infringement of the '763 patent. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 115 of the FAC.

116. Paragraph 116 of the FAC states legal conclusions to which no response is required. To the extent that a response is required, Amneal states that the '763 patent speaks for itself and is the best source for its content, subject to the Court's claim construction. Amneal denies any remaining allegations in Paragraph 116 of the FAC.

117. Denied.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

123. Denied.

124. Amneal admits that it was aware of the '763 patent and its listing in the FDA's "Orange Book" for Xifaxan®, 550 mg tablets on the date it sent the Amneal Notice Letter. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 124 of the FAC.

125. Denied.

[ANSWER TO] PRAYER FOR RELIEF

Amneal denies that Plaintiffs are entitled to judgment and any relief sought by the FAC in paragraphs (i)-(viii) of their prayer for relief or otherwise.

AFFIRMATIVE DEFENSES

Amneal, without prejudice to the denials set forth in its Answer, further alleges the following defenses to Plaintiffs' FAC. Amneal reserves the right to supplement this Answer, including the right to assert additional defenses as more information is learned through discovery, claim construction, and/or any further investigation in this case. Amneal does not assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

FIRST DEFENSE
(Non-infringement of the Patents-in-suit)

The manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Product, that is the subject of ANDA No. 218862, has not, does not, and will not infringe any valid and enforceable claim of the '571 patent, '912 patent,'196 patent, '949 patent, '904 patent, '968

patent, and '763 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any manner.

SECOND DEFENSE
(Invalidity and/or Unenforceability of the Patents-in-suit)

Each asserted claim of the '571 patent, '912 patent, '196 patent, '949 patent, '904 patent, '968 patent, and '763 patent is invalid and/or unenforceable for failure to meet the requirements of patentability set forth in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity and/or unenforceability, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

THIRD DEFENSE
(Prosecution History Estoppel)

Plaintiffs' claims are barred in whole or in part by the doctrine of prosecution history estoppel. Under the doctrine of prosecution history estoppel, Plaintiffs cannot use the doctrine of equivalents to reclaim claim scope surrendered during prosecution.

FOURTH DEFENSE
(Failure to State a Claim)

The FAC fails to state a claim upon which relief may be granted and must be dismissed to the extent Amneal has not infringed, and will not infringe any valid and enforceable claim of the '571 patent, '912 patent, '196 patent, '949 patent, '904 patent, '968 patent, and '763 patent.

FIFTH DEFENSE
(Not an Exceptional Case)

Plaintiffs are not entitled to a finding that this case is exceptional or to attorneys' fees under 35 U.S.C. § 285, pursuant to the Court's inherent power or pursuant to any other basis.

SIXTH DEFENSE
(No Injunctive Relief)

Plaintiffs are not entitled to injunctive relief because Plaintiffs cannot prove: (i) that they have suffered irreparable injury; (ii) that there is no adequate remedy at law; (iii) that a remedy in equity is warranted; and (iv) that the public interest warrants an injunction.

SEVENTH DEFENSE
(Reservation of Rights)

Amneal specifically reserves the right to assert each and every other defense that may become evident in the course of discovery.

WHEREFORE, Amneal prays that this Court enter an order:

A. Dismissing the FAC, with prejudice, and denying Plaintiffs the relief requested in the FAC and any relief whatsoever;

B. Declaring this case exceptional and awarding Amneal reasonable attorneys' fees;

C. Awarding Amneal its costs; and

D. Granting such other and further relief as this Court may deem just.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Further responding to the FAC, pursuant to Fed. R. Civ. P. 13, Defendants-Counterclaim Plaintiffs Amneal Pharmaceuticals of New York, LLC ("Amneal NY") and Amneal EU, Limited ("Amneal EU") (together, "Amneal") allege the following counterclaims, without admitting any allegations of the FAC not otherwise admitted and without assuming the burden when such burden would otherwise be on Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd.,

Alfasigma S.p.A., and Bausch Health Ireland, Ltd. (collectively, "Counterclaim Defendants" or "Salix").

NATURE OF THE ACTION

1. These Counterclaims seek a declaratory judgment that Amneal's submission of Abbreviated New Drug Application ("ANDA") No. 218862 does not and will not infringe any valid and enforceable claim 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 "counterclaim patents-in-suit"), and that each and every claim of the counterclaim patents-in-suit is invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

PARTIES

2. Amneal NY is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Blvd., 3rd Floor, Bridgewater, New Jersey 08807. Amneal NY is a wholly-owned subsidiary of Amneal LLC.

3. Amneal EU 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.

4. Upon information and belief and based on the allegations in the FAC, 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. Upon information and belief and based on the allegations in the FAC, 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. Upon information and belief and based on the allegations in the FAC, 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.

7. Upon information and belief and based on the allegations in the FAC, 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.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq*.

9. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-2202, 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5) because this is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that the counterclaim patents-in-suit are not and will not be infringed; and if any claim of the counterclaim patents-in-suit were to be interpreted more broadly than this broadest reasonable construction, the claims would be invalid.

10. This Court has personal jurisdiction over Counterclaim Defendants based, *inter alia*, on the filing by Counterclaim Defendants of this lawsuit in this jurisdiction.

11. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), 1400(b), and because Counterclaim Defendants have voluntarily submitted to venue in this Court by filing the instant action in this jurisdiction.

THE CONTROVERSY

I. NATURE OF THE CASE

12. These Counterclaims seek injunctive relief, treble damages, and other relief under federal and state antitrust laws to remedy plainly anticompetitive conduct by Salix. Salix's conduct complained of herein had, and continues to have, the intended effect of foreclosing competition in the sale of an important prescription medicine, rifaximin 550 mg tablets indicated for the treatment of, among other things, irritable bowel syndrome with diarrhea (IBS-D) in adults, marketed under the trade name Xifaxan® ("Xifaxan®"). Salix's anticompetitive scheme has had the effect of preserving its monopoly position for that medicine and inflicting substantial harm to consumers by denying the marketplace lower-priced competition from Xifaxan's® therapeutically equivalent generic version.

13. Facing the prospect of generic competition, Salix filed this sham patent infringement action against Amneal in an attempt to exploit a feature of the Hatch-Waxman Act through which the manufacturer of a branded drug product can block Food & Drug Administration ("FDA") approval of a rival generic product for thirty (30) months by filing a patent-infringement suit. Salix has unlawfully perverted this regulatory provision—designed to allow patent holders an opportunity to pursue legitimate, well-grounded patent infringement claims—by filing an objectively baseless patent infringement suit with the sole purpose of delaying FDA approval for Amneal's product and prolonging the monopoly enjoyed by Salix's product, Xifaxan®. The antitrust laws, however, condemn such tactics.

14. Salix's patent-infringement suit against Amneal is objectively baseless for at least two reasons. First, the Asserted Polymorph Patents[1] do not cover Xifaxan®, which consists of rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the FDA publication entitled "Approved Drug Products and Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book").

15. Second, the Asserted IBS Patents[2] consist of method of treatment claims that are nearly identical in scope to related patent claims that have been invalidated as obvious by the Federal Circuit. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024).

16. The reason for Salix's sham litigation is straightforward: its instant lawsuit has forestalled and continues to forestall generic competition—this time by Amneal—by triggering an automatic 30-month stay on the FDA's authority to approve Amneal's generic product. But for this anticompetitive conduct, Amneal could receive final FDA approval earlier than 30 months and launch a therapeutically equivalent generic product—at a price substantially lower than Salix's pricing.

17. Through its unlawful and exclusionary conduct, Salix has foreclosed competition and unlawfully maintained its monopoly, denying consumers the benefit of lower-cost, therapeutically equivalent, AB-rated generic alternatives, and causing Amneal competitive injury, including the cost of defending this baseless lawsuit and the loss of millions of dollars in revenue that will result if FDA approval of its ANDA Product (defined below) is delayed.

[1] The "Asserted Polymorph Patents" include the following patents: the '196 patent; the '949 patent; the '904 patent; the '968 patent; and the '763 patent.
[2] The "Asserted IBS Patents" include the following patents: the '571 patent and the '912 patent.

II. REGULATORY BACKGROUND

18. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. ("FDCA" or "Act"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States.

19. Pursuant to the FDCA, any company that wishes to sell a new drug in the United States must seek FDA approval by filing a New Drug Application ("NDA") with the FDA. As part of that application, the submitter of the NDA must provide the FDA with information identifying each patent "for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug" that is the subject of the NDA, and that either (I) "claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent;" or (II) "claims a method of using such drug for which approval is sought or has been granted in the application." 21 U.S.C. § 355(b)(1)(A)(viii); *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1377 (Fed. Cir. 2023).

20. Submission of information on patents that do not meet these criteria is prohibited by law. 21 U.S.C. § 355(c)(2) ("Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.").

21. Upon approval of an NDA, the patent information submitted to the FDA by the NDA holder under 21 U.S.C. § 355(b)(1)(A)(viii) is published by the FDA in a publicly available online database commonly referred to as the Orange Book. *See Jazz Pharms., Inc.*, 60 F.4th at 1377. The Orange Book is located at the following web address: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

22. "[T]he FDA does not verify that submitted patents actually meet the statutory listing criteria, nor does the FDA proactively remove improperly listed patents" from the Orange Book. *See Jazz Pharms., Inc.*, 60 F.4th at 1378. Rather, the FDA's role with respect to the Orange Book patent listings is "purely ministerial." *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (noting FDA arguments that (i) FDA does not have a duty to determine "whether the patent claims the drug," (ii) "FDA has a only a ministerial role in the listing process," and (iii) "it is the responsibility of the NDA holder to determine whether a patent claims the drug or a method of using the drug that is the subject of the NDA for purposes of Orange Book listing"); *Jazz Pharms, Inc.*, 60 F.4th at 1378.

23. The FDA has adopted a regulation, 21 C.F.R. § 314.53(f), codifying and implementing its position that its duties with respect to Orange Book listings are purely ministerial. *Apotex, Inc.*, 347 F.3d at 1347. Under this regulation, a third party may dispute an Orange Book listing, but the FDA will not modify the listing unless the NDA holder itself requests the modification. *See* 21 C.F.R. § 314.53(f); *Apotex, Inc.*, 347 F.3d at 1347.

24. When an ANDA is submitted to the FDA seeking permission to market a generic version of an approved NDA product, if there are no patents listed in the Orange Book for the corresponding NDA product, the ANDA must include a certification that no such patent information has been filed. *See* 21 U.S.C. § 355 (j)(2)(A)(vii)(I). This is known as a "Paragraph I Certification."

25. If, however, there are any patents listed in the Orange Book for the corresponding NDA, for each patent listed in the Orange Book for the relevant NDA product, the ANDA must include a certification for each patent stating (a) that the patent has expired (a "Paragraph II Certification"), (b) when the patent will expire (a "Paragraph III Certification"), or (c) that the

patent is invalid or will not be infringed by the manufacture, use or sale of the ANDA product (a "Paragraph IV Certification"). 21 U.S.C. §355 (j)(2)(A)(vii)(II)-(IV).

26. If the ANDA contains only Paragraph I Certification(s) and/or Paragraph II certification(s), the FDA may approve the ANDA immediately. 21 U.S.C. § 355 (j)(5)(B)(i).

27. If the ANDA contains Paragraph III Certifications and no Paragraph IV Certification, the FDA may approve the ANDA on the patent expiration date certified in the Paragraph III certification. 21 U.S.C. §355 (j)(5)(B)(ii).

28. If an ANDA contains one or more Paragraph IV Certifications, the ANDA applicant must provide notice of same to the NDA holder and owner(s) of the corresponding patent(s) and provide a "detailed statement of the factual and legal basis for the opinion that the patent is invalid or will not be infringed." 21 U.S.C. §355 (j)(2)(B)(iv)(II).

29. The filing of a Paragraph IV Certification is treated under the patent law as an act of technical infringement that provides the brand company an opportunity to sue. *See* 35 U.S.C. § 271(e)(2)(A). If the NDA holder brings a patent infringement lawsuit within 45 days after it receives the notice of the Paragraph IV filing, the FDA's approval of the corresponding ANDA will automatically be stayed for 30 months, unless the patent litigation is resolved sooner. 21 U.S.C. §355 (j)(5)(B)(iii).

30. If an infringement action is brought against an ANDA applicant in response to receiving notice of a Paragraph IV Certification, the ANDA applicant may "assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the [NDA] holder." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

III. FACTUAL AND PROCEDURAL BACKGROUND

A. Xifaxan®

31. Salix Pharmaceuticals holds the approved New Drug Application for No. 021361for Xifaxan® (rifaximin) 550 mg tablets.

32. Xifaxan® 550 mg tablets are indicated for (i) "[t]reatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adult and pediatric patients 12 years of age and older," (ii) "[r]eduction in risk of overt hepatic encephalopathy recurrence in adults," and (iii) "[t]reatment of irritable bowel syndrome with diarrhea (IBS-D) in adults."

33. In its FAC against Amneal, Salix alleged that Counterclaim Defendant Salix Pharmaceuticals, Inc. is the assignee of the '571 patent and the '912 patent.

34. In its FAC against Amneal, Salix alleged that Counterclaim Defendant AlfaSigma, S.p.A. is the assignee of the '196 patent, the '949 patent, the '904 patent, the '968 patent, and the '763 patent.

35. In its FAC against Amneal, Salix alleged that Counterclaim Defendant Bausch Health Ireland Ltd. and Counterclaim Defendant 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, and that Counterclaim Defendant Salix Pharmaceuticals, Inc. is the sole distributor in the United States of Xifaxan® tablets.

36. Amneal submitted ANDA No. 218862 to the FDA, seeking approval to engage in the commercial manufacture, use, and/or sale of rifaximin 550 mg tablets (the "Amneal ANDA Product"). Amneal's ANDA includes a Paragraph IV Certification that the counterclaim patents-

in-suit are invalid, unenforceable, and/or not infringed by the Amneal ANDA Product. The only indication for which Amneal's ANDA seeks FDA approval is for the treatment of IBS-D.

37. On February 27, 2024, Amneal sent a confidential notice of the Paragraph IV certification to Salix (the "Notice Letter").

38. On or around April 5, 2024, Salix filed this lawsuit, alleging that Amneal infringes the counterclaim patents-in-suit.

39. Salix's lawsuit against Amneal triggered a 30-month stay of final FDA approval of Amneal's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay, which is imposed only where an NDA holder files a patent infringement suit within 45 days of receiving notice of a Paragraph IV certification, is not set to expire until August 29, 2026—long after Amneal expects to be able to launch the Amneal ANDA Product.

B. Pursuit of A Baseless Patent Litigation: Salix's Improper Orange Book Listing for the Asserted Polymorph Patents and Suit on Invalid IBS Patents

40. At the time Amneal submitted its ANDA seeking FDA approval to market a generic version of Xifaxan®, all seven asserted patents, which include the Asserted Polymorph Patents and the Asserted IBS Patents, were listed, among others, in the Orange Book for Xifaxan®.

41. Upon crystallization, rifaximin may take the form of one of several crystalline structures. The various polymorphs of rifaximin include Polymorph α (alpha), Polymorph β (beta), Polymorph γ (gamma), Polymorph δ (delta), and Polymorph ε (epsilon). Different polymorphs, even of the same molecule, like rifaximin, may impart different physical and chemical properties compared to one another. On information and belief, Salix's rifaximin tablets, 550 mg, which it sells under the trade name Xifaxan®, consists of Polymorph α (alpha). The claims of the Asserted Polymorph Patents, however, are directed solely to Polymorph δ

(delta) and Polymorph ε (epsilon) structures. Therefore, the Asserted Polymorph Patents do not cover Xifaxan®, which consists of rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the Orange Book.

42. At the time of filing this Answer, Affirmative Defenses, and Counterclaims, all five Asserted Polymorph Patents remained listed in the Orange Book for Xifaxan®.

43. Because Salix improperly listed the Asserted Polymorph Patents in the Orange Book, Amneal was required to submit Paragraph IV Certifications as to each of the Asserted Polymorph Patents (rather than a Paragraph I Certification) in order to seek approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product prior to the expiration of the Asserted Polymorph Patents. The Amneal Notice Letter notified Salix that Amneal had submitted to the FDA Amneal's ANDA including Paragraph IV Certifications as to each of the Asserted Patents.

44. In response, Salix filed this lawsuit under 35 U.S.C. § 271(e), alleging Amneal infringed the Asserted Patents. The lawsuit triggered the Hatch-Waxman Act's 30-month stay of final approval of Amneal's ANDA, which occurs only when an NDA holder files suit within 45 days of receiving notice of an ANDA with a Paragraph IV Certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii). But for Salix's improper Orange Book listing on the Asserted Polymorph Patents, Amneal would not have submitted Paragraph IV Certifications with respect to the Asserted Polymorph Patents, and no 30-month stay would be imposed solely with respect to the Asserted Polymorph Patents.

45. Similarly, but for Salix's decision to file this baseless lawsuit within 45 days of receipt of the Amneal Notice Letter, no 30-month stay would be imposed.

46. Salix's patent infringement claims asserted in this lawsuit against Amneal are objectively baseless and were brought in bad faith. No reasonable litigant could expect to secure favorable relief against Amneal on the merits because Amneal's ANDA Product does not infringe any of the claims of the Asserted Patents and the Asserted Patents are invalid.

47. Specifically, as to the Asserted Polymorph Patents, they do not cover Xifaxan®, rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the Orange Book. Moreover, for identical reasons that related Salix's rifaximin polymorph patents were held invalid in *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1067 (Fed. Cir. 2024), the Asserted Polymorph Patents are also likely invalid as obvious.

48. In addition, for the reasons discussed below, Salix's infringement claims with respect to the Asserted IBS Patents are objectively baseless.

49. On March 26, 2020, Salix sued Norwich Pharmaceuticals, Inc. and Alvogen PB Research and Development LLC (together, "Norwich"), alleging that Norwich's proposed ANDA product, which referenced Salix's Xifaxan®, 550 mg tablets, infringed 26 Orange Book patents. *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 1:20-cv-00430-RGA, Dkt. 1, 59.

50. "Irritable bowel syndrome ('IBS') is characterized by symptoms including abdominal pain, bloating, frequency, urgency, gas, and changed bowel habits, such as diarrhea, constipation, or alternating diarrhea and constipation. Subtypes of IBS include IBS with diarrhea (IBS-D), IBS with constipation (IBS-C), or IBS with alternating diarrhea and constipation (IBS-A). The IBS-D subtype comprises about one-third of IBS patients. IBS may be caused, for example, by abnormal motility, abnormal muscular coordination, changes in the microbiome in the colon or small intestine, intolerance to certain foods, or psychological factors." *Salix*

Pharms., Ltd. v. Norwich Pharms., Inc., Civ. No. 20-430-RGA, 2022 WL 3225381, at *16 (D. Del. Aug. 10, 2022).

51. Before trial, Salix narrowed its case, choosing to assert only two patents directed to treating IBS: claim 2 of U.S. Patent No. 8,309,569 and claim 3 of U.S. Patent No. 10,765,667. *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 1:20-cv-00430-RGA, Dkt. 179.

52. "Asserted Claim 3 of the '667 patent is a dependent claim that has three elements: (1) administering 550 mg of rifaximin three times a day (TID) for 14 days; (2) to treat one or more symptoms of IBS-D; (3) in a subject 65 years of age or older. Asserted Claim 2 of the '569 patent is a dependent claim with two elements: (1) administering 550 mg of rifaximin TID for 14 days [for the treatment of IBS-D]; and (2) after stopping rifaximin, achieving a durability of response that comprises about 12 weeks of adequate relief of symptoms." *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, Civ. No. 20-430-RGA, 2022 WL 3225381, at *16 (D. Del. Aug. 10, 2022).

53. At trial, relying on the RFIB 2001 Protocol[3] and Pimentel 20006[4] prior art references, the court found that the prior art disclosed all the limitations of the asserted IBS-D claims and that a skilled artisan would have been motivated to combine those two references with a reasonable expectation of success. *Id*. at *17.

[3] The "RFIB 2001 Protocol" (DTX 340) was a Phase II trial designed to administer rifaximin to patients aged 18 and over, 550-2,220 mg per day for 14 days for the treatment of IBS-D. The protocol included the outcome measures of providing adequate relief of symptoms and evaluating a durability of response over a 12-week post-treatment period. *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, Civ. No. 20-430-RGA, 2022 WL 3225381, at *19 (D. Del. Aug. 10, 2022).

[4] "Pimentel 2006" refers to a 2006 study published on the use of rifaximin to treat IBS. It was a randomized, double-blind, placebo-controlled study that administered rifaximin, 400 mg TID for 10 days, to treat IBS patients aged 18-65. "Pimentel 2006 taught, 'rifaximin resulted in statistically greater global improvement in IBS than placebo,' and '[i]mprovements were sustained through 10 weeks of follow-up" after 10 days of treatment.'" *Id*.

54. The trial court's findings with respect to the obviousness of the IBS-D asserted patent claims were affirmed in a precedential decision on appeal. *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024) ("We accordingly affirm the district court's determination that Norwich established that the IBS-D claims would have been obvious in view of the Protocol and Pimentel.").

55. Salix now asserts nearly identical method of treating claims against Amneal. For example, the sole independent claim of the '571 patent reads: "A method of treating bloating associated with diarrhea-predominant irritable bowel syndrome (dIBS) in a female subject, said method comprising administering, 550 mg of rifaximin TID for 14 days to the female subject, thereby treating bloating associated with dIBS in the female subject." The sole independent claim of the '912 patent reads: "A method of treating one or more symptoms of irritable bowel syndrome (IBS) in a female subject, said method comprising administering, 550 mg of rifaximin TID for 14 days to the female subject, thereby treating one or more symptoms of IBS in the female subject." Dependent claim 3 of the '912 patent reads: "The method of claim 1, wherein the IBS is diarrhea-predominant IBS."

56. The method of treating patent claims that Salix now asserts against Amneal are nearly identical to the method of treating patent claims held invalid in the *Norwich* litigation. The only difference between the now invalid IBS-D patent claims and the '571 and '912 patent claims here are that the former are directed to treating IBS-D, including in "subject[s] 65 years of age or older," while the latter are directed to treating IBS, including IBS-D, in "a female subject."

57. On May 2, 2024, counsel for Amneal contacted counsel for Salix to inquire whether Salix intended to withdraw its allegations of infringement of the '571, '912, and

(originally asserted) '384 method of treating IBS patents in view of the recent Federal Circuit decision in the *Norwich* litigation. Counsel for Salix responded that it "carefully considered" Amneal's inquiry but would not agree to drop the claims of the '571, '912, and '384 patents. Thereafter, Salix filed its FAC and withdrew its allegations of infringement for the '384 patent.

58. In view of the Federal Circuit's decision finding claim 3 of the '667 patent and claim 2 of the '569 patent invalid as obvious in the Norwich litigation, it would be objectively baseless for Salix to continue to assert the nearly identical method of treating IBS claims in the '571 and '912 patents against Amneal.

C. But For Salix's Baseless Lawsuit, Amneal Would Have Launched a Lower-cost Therapeutically Equivalent Generic Version Prior to the Expiration of the 30-Month Stay

59. If Salix had not filed this baseless lawsuit, Amneal would have been able to launch a therapeutically equivalent, AB-rated generic version of Xifaxan® as soon as the FDA approves its ANDA.

60. Amneal planned to price its generic version of Xifaxan® at a substantial discount compared to Xifaxan®, providing consumers with a lower cost, but therapeutically identical, alternative to branded Xifaxan®.

61. Generic drugs are typically sold at substantial discounts from the price of the branded reference-listed drug ("RLD"). The first AB-rated generic drug that enters the market is generally priced at a significant discount to the RLD and, as additional AB-rated generic drugs enter the market, generic drug prices continue to fall.

62. Competition from generic drugs generates large savings for consumers. The Generic Pharmaceutical Association reported that use of generic versions of brand-name drugs saved the U.S. healthcare system $217 billion in 2012 alone.

63. Absent Salix's unlawful anticompetitive conduct, Amneal will likely capture a significant volume of generic sales of Xifaxan® within days of FDA approval. As with prior generic products that Amneal has launched in the United States, Amneal expects that pharmacies and other customers would place large orders of Amneal's generic product on the first day it becomes available, as these customers would have an incentive to build up a sufficient inventory of generic Xifaxan® to meet demand.

64. Salix's exclusionary actions in filing and prosecuting this baseless patent-infringement lawsuit constitute wrongful and unlawful exclusionary conduct. Its conduct has the purpose and effect of blocking competition by delaying the entry of lower-cost, therapeutically equivalent, AB-rated generic substitutes for branded Xifaxan®.

D. Salix's Monopoly Power in the Relevant Market

65. At all relevant times, Salix had monopoly power in the market for Xifaxan®, and its generic equivalents because it had the power to raise or maintain the price of Xifaxan® as well as the power to exclude competitors.

66. At all times during Salix's monopoly, a small but significant, non-transitory increase to the price of Xifaxan®, and its generic equivalents would not have caused Salix to suffer a significant loss of sales.

67. On information and belief, Xifaxan®, and its generic equivalents do not exhibit significant, positive cross-elasticity of demand with respect to price with any other product prescribed for the treatment of IBS-D. Notwithstanding the commercialization of other IBS-D treatments, Salix continued to charge supracompetitive prices and exclude competitors.

68. On information and belief, Salix sold Xifaxan® at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

69. Salix has, and has exercised, the power to exclude competition to Xifaxan®, and its generic equivalents.

70. Salix enjoyed high barriers to entry with respect to the generic versions of Xifaxan®, including FDA's regulatory requirements and the substantial time and expense required to develop an ANDA for a generic product therapeutically equivalent and AB-rated Xifaxan®.

71. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Salix's ability to control prices of Xifaxan® and to exclude relevant competitors, without the need to show the relevant antitrust market. The direct evidence consists of, among other things, (a) the fact that additional competing generic equivalents would have entered the market at substantial discounts to the brand version but for Salix's anticompetitive conduct; and (b) Salix's supracompetitive pricing for Xifaxan®, and Xifaxan® AG.

72. To the extent proof of monopoly power by defining a relevant product market is required, Amneal alleges that the relevant antitrust market is the market for Xifaxan®, and its generic equivalents. Xifaxan®, and its generic equivalents are not reasonably interchangeable with other products due to the distinct qualities and characteristics of Xifaxan®, which distinguish it from other drugs indicated to treat IBS-D prior to the availability of Xifaxan®, like Lotronex® and Viberzi®. For example, Lotronex® (alosetron) is intended only for severe cases of IBS-D in women who have not responded to other treatments, and—unlike Xifaxan®—is not approved for use by men. See https://accessdata.fda.gov/drugsatfda_docs/label/2008/021107s013lbl.pdf. Similarly, the active ingredient in Viberzi®, eluxadoline, is listed in Schedule IV of the Controlled Substances Act, and clinical trial data suggest that eluxadoline may produce psychological dependence. See

https://rxabbvie.com/pdf/viberzi/pi.pdf, at Section 9. Accordingly, Xifaxan® and its generic equivalents are appropriately considered as a market of their own.

73. The relevant geographic market is the United States. The FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occurs on a nationwide basis, establishes the boundaries of the geographic market.

74. Thus, for purposes of this lawsuit, the market for the sale of Xifaxan® and its generic equivalents in the United States (the "Relevant Market") constitutes a relevant market.

75. Upon information and belief, at all relevant times Salix had a 100% share of the Relevant Market.

76. On information and belief, Salix was able to set prices of Xifaxan® above that which would be charged in a competitive market.

77. Salix possesses monopoly power in the Relevant Market, as evidenced by, among other factors, its prior pricing actions and dominant market share.

E. Antitrust Impact and Impact on Interstate Commerce

78. Amneal plans to launch the Amneal ANDA Product immediately upon receipt of final FDA approval.

79. Via a letter dated February 9, 2024, the FDA informed Amneal that it has set a goal date of October 26, 2024, for review of Amneal's ANDA. Amneal reasonably expects to receive FDA approval on or after October 26, 2024. Because of Salix's anticompetitive conduct, that approval will be tentative, meaning that Amneal will need to wait until expiration of the 30-month stay to receive final approval and launch the Amneal ANDA Product. The approval on or after October 26, 2024, would be final but for Salix's anticompetitive conduct.

80. Amneal has begun preparing to make multi-million-dollar investments specifically tailored to the successful launch of Amneal's rifaximin 550 mg ANDA product. Amneal has begun preparing to make those investments—several million dollars for active pharmaceutical ingredient procurement and the cost for manufacturing commercial batches for retail and government sales channels, and at least an additional couple million dollars in operational and production costs—at least six months prior to its expected launch date.

81. Salix's scheme to maintain its monopoly in the Relevant Market and charge supracompetitive prices includes delaying Amneal's entry through (i) Orange Book abuse and (ii) engaging in sham litigation. Salix's anticompetitive scheme has had a direct, substantial, and adverse effect on Amneal and interstate competition in the Relevant Market by maintaining monopoly power, increasing prices, artificially creating barriers to entry, and delaying competition in the Relevant Market.

82. By impeding competition from generic equivalent products, including Amneal's ANDA Product, Salix's anticompetitive scheme has allowed (and, unless restrained by this Court, will continue to allow) Salix to maintain and extend its monopoly power in the Relevant Market and to sell Xifaxan® at artificially inflated monopoly prices.

83. Salix's anticompetitive scheme has harmed the competitive process and has had a substantial effect on interstate commerce, as it has allowed Salix to charge supracompetitive prices. But for this anticompetitive conduct, consumers and payors would have enjoyed the benefits of lower-priced generic competition from Amneal earlier than the expiration of the 30-month stay. Instead, as a result of Salix's strategies, which include improper listing of the Asserted Polymorph Patents in the Orange Book and engaging in sham litigation, consumers and payors have been forced to pay monopoly prices for Salix's Xifaxan®. The impact of Salix's

anticompetitive conduct, and the accompanying supracompetitive pricing, is felt throughout the health care industry, impacting pharmaceutical competitors, healthcare providers, insurers, and other direct purchasers, intermediaries, and consumers.

84. Amneal has suffered, and will continue to suffer, harm as a result of Salix's anticompetitive conduct. That harm includes:

a. Loss of future sales and profits due to being foreclosed from selling in the Relevant Market;

b. The large amount of time and expense associated with having to fight baseless, sham patent litigation, including sham litigation based on patents that were improperly listed in the Orange Book; and

c. A delay in Amneal's ability to recoup its investment in procuring active pharmaceutical ingredient, the cost for manufacturing commercial batches for retail and government sales channels, and other operational and production costs for the Amneal ANDA Products.

85. A claimant satisfies the injury-in-fact requirement of standing where, as here, "the threatened injury is real, immediate, and direct." *See Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 930 (N.D. Ill. 2010) (quoting *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008)); *accord Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 118 F. Supp. 3d 646, 653 (D.N.J. 2015) ("[T]he alleged injuries must, as with all types of standing, be both real and immediate, not conjectural or hypothetical." (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983))).

86. "[T]he creation of 'an independent barrier to the drug market' by a brand drug company 'that deprives [the generic company] of an economic opportunity to compete' satisfies the injury-in-fact and causation requirements of Article III standing." *See Pfizer Inc.*, 726 F. Supp 2d at 930 (quoting *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008)).

87. The injury to Amneal is immediate. Amneal is already spending time and money to litigate this baseless and sham patent litigation. Because Salix filed the instant patent suit, alleging infringement of patents improperly listed in the Orange Book, Amneal's final FDA approval is subject to the automatic 30-month stay. Based on the date which Salix filed the present lawsuit, Amneal's ANDA would not be eligible for final approval until August 29, 2026. Accordingly, from the date of Amneal's tentative approval through August 29, 2026, Amneal's ANDA will be ineligible for final approval, and Amneal therefore will be deprived of the ability to launch its generic product, as a result of Salix's anticompetitive conduct.

88. As a result of Salix's improper listing of the Asserted Polymorph Patents and sham litigation on the IBS Patents, Amneal has already suffered and will imminently suffer the injuries outlined above.

89. Salix's anticompetitive conduct, as alleged herein, is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state action doctrine or any statute of limitations.

90. There is and was no legitimate, procompetitive justification for Salix's conduct. Even if there was some conceivable and cognizable justification, Salix's conduct was not necessary to achieve such a purpose, and, in any event, any procompetitive effects would be outweighed by the scheme's anticompetitive effects on Amneal, competition, and consumers.

FIRST COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '571 Patent)

91. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-90 as if fully set forth herein.

92. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding the invalidity of the '571 patent.

93. Every claim of the '571 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq.*, including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Amneal's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

94. By way of non-limiting example, one or more claims of the '571 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- "Study to Assess the Efficacy and Safety of Rifaximin Administered BID in the Treatment of Patients With Diarrhea-Associated Irritable Bowel Syndrome," NCT00269412, available at https://clinicaltrials.gov/study/NCT00269412 ("RFIB2001 Study Protocol");
- Pimental *et al*. 2006, "The Effect of a Nonabsorbed Oral Antibiotic (Rifaximin) on the Symptoms of the Irritable Bowel Syndrome," *Annals Internal Med*., 145(8):557-63 ("Pimental 2006");
- Barrett *et al*. 2006, "Benefits of the Antibiotic Rifaximin as Empiric Therapy in Patients with Irritable Bowel Syndrome," *Am. J. Gastroenterology*, 1(9) ("Barrett");
- Sharara *et al*., 2006 "A Randomized Double-Blind Placebo-Controlled Trial of Rifaximin in Patients with Abdominal Bloating and Flatulence," *Am. J. Gastroenterology*, 101(2):326-33 ("Sharara"); and/or
- Scarpellini *et al*. 2007, "High dosage rifaximin for the treatment of small intestinal bacterial overgrowth," *Alimentary Pharm. & Therapeutics*, 25(7):781-86 ("Scarpellini").

95. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that patent claims directed to the method of treating IBS-D using rifaximin for fourteen days wherein 1650 mg of

rifaximin is administered at 550 mg three times per day were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024).

96. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that the asserted claims of the '571 patent are invalid.

SECOND COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '571 Patent)

97. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-96 as if fully set forth herein.

98. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding whether Amneal's submission of ANDA No. 218862 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal ANDA product has infringed or will infringe any valid and enforceable claim of the '571 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

99. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '571 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '571 patent are invalid at least for the reasons provided in Amneal's confidential Notice Letter.

100. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '571 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Amneal ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '571 patent.

THIRD COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '912 Patent)

101. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-100 as if fully set forth herein.

102. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding the invalidity of the '912 patent.

103. Every claim of the '912 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq.*, including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Amneal's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

104. By way of non-limiting example, one or more claims of the '912 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- RFIB2001 Study Protocol;
- Pimental 2006;
- Cuoco *et al*. 2006, "Small intestine bacterial overgrowth in irritable bowel syndrome: a retrospective study with rifaximin," *Minerva Gastroenterologica e Dietologica*, 52(1):89-95 ("Cuoco");
- Barrett;
- Sharara; and/or
- Scarpellini.

105. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that patent claims directed to the method of treating IBS-D using rifaximin for fourteen days wherein 1650 mg of rifaximin is administered at 550 mg three times per day were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1064 (Fed. Cir. 2024).

106. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that the asserted claims of the '912 patent are invalid.

FOURTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '912 Patent)

107. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-106 as if fully set forth herein.

108. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding whether Amneal's submission of ANDA No. 218862 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal ANDA product has infringed or will infringe any valid and enforceable claim of the '912 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

109. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '912 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '912 patent are invalid at least for the reasons provided in Amneal's confidential Notice Letter.

110. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '912 patent either literally or under the

doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the Amneal ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '912 patent.

FIFTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '196 Patent)

111. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-110 as if fully set forth herein.

112. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding the invalidity of the '196 patent.

113. Every claim of the '196 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq.*, including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Amneal's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

114. By way of non-limiting example, one or more claims of the '196 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- U.S. Patent No. 4,557,866 ("Cannata");
- U.S. Patent No. 4,341,785 ("Marchi"); and/or
- Normix® (rifaximin) Product Label ("Normix® label").

115. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that a skilled artisan

would have had a reasonable expectation of success in characterizing the crystalline rifaximin in the prior art for potential polymorphism using routine, conventional methods and skill, and that the rifaximin polymorph patents-in-suit were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024).

116. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that the asserted claims of the '196 patent are invalid.

SIXTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '196 Patent)

117. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-116 as if fully set forth herein.

118. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding whether Amneal's submission of ANDA No. 218862 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal ANDA product has infringed or will infringe any valid and enforceable claim of the '196 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

119. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '196 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '196 patent are invalid at least for the reasons provided in Amneal's confidential Notice Letter.

120. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '196 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the

Amneal ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '196 patent.

SEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '949 Patent)

121. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-120 as if fully set forth herein.

122. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding the invalidity of the '949 patent.

123. Every claim of the '949 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Amneal's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

124. By way of non-limiting example, one or more claims of the '949 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- Cannata;
- Marchi; and/or
- Normix® label.

125. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that a skilled artisan would have had a reasonable expectation of success in characterizing the crystalline rifaximin in

the prior art for potential polymorphism using routine, conventional methods and skill, and that the rifaximin polymorph patents-in-suit were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024).

126. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that the asserted claims of the '949 patent are invalid.

EIGHTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '949 Patent)

127. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-126 as if fully set forth herein.

128. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding whether Amneal's submission of ANDA No. 218862 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal ANDA product has infringed or will infringe any valid and enforceable claim of the '949 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

129. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '949 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '949 patent are invalid at least for the reasons provided in Amneal's confidential Notice Letter.

130. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '949 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the

Amneal ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '949 patent.

NINTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '904 Patent)

131. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-130 as if fully set forth herein.

132. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding the invalidity of the '904 patent.

133. Every claim of the '904 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Amneal's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

134. By way of non-limiting example, one or more claims of the '904 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- Cannata;
- Marchi; and/or
- Normix® label.

135. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that a skilled artisan would have had a reasonable expectation of success in characterizing the crystalline rifaximin in

the prior art for potential polymorphism using routine, conventional methods and skill, and that the rifaximin polymorph patents-in-suit were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024).

136. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that the asserted claims of the '904 patent are invalid.

TENTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '904 Patent)

137. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-136 as if fully set forth herein.

138. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding whether Amneal's submission of ANDA No. 218862 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal ANDA product has infringed or will infringe any valid and enforceable claim of the '904 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

139. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '904 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '904 patent are invalid at least for the reasons provided in Amneal's confidential Notice Letter.

140. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '904 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the

Amneal ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '904 patent.

ELEVENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '968 Patent)

141. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-140 as if fully set forth herein.

142. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding the invalidity of the '968 patent.

143. Every claim of the '968 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Amneal's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

144. By way of non-limiting example, one or more claims of the '968 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- Cannata;
- Marchi; and/or
- Normix® label.

145. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that a skilled artisan would have had a reasonable expectation of success in characterizing the crystalline rifaximin in

the prior art for potential polymorphism using routine, conventional methods and skill, and that the rifaximin polymorph patents-in-suit were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024).

146. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that the asserted claims of the '968 patent are invalid.

TWELFTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '968 Patent)

147. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-146 as if fully set forth herein.

148. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding whether Amneal's submission of ANDA No. 218862 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal ANDA product has infringed or will infringe any valid and enforceable claim of the '968 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

149. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '968 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '968 patent are invalid at least for the reasons provided in Amneal's confidential Notice Letter.

150. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '968 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the

Amneal ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '968 patent.

THIRTEENTH COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '763 Patent)

151. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-150 as if fully set forth herein.

152. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding the invalidity of the '763 patent.

153. Every claim of the '763 patent is invalid for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity, such as obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto, for at least the reasons set forth in Amneal's confidential Notice Letter, and for such other reasons as will likely have evidentiary support after further investigation or discovery.

154. By way of non-limiting example, one or more claims of the '763 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of the following prior art references, alone or in combination:

- Cannata;
- Marchi; and/or
- Normix® label.

155. On April 11, 2024, in a precedential opinion, the Court of Appeals for the Federal Circuit affirmed the District Court for the District of Delaware's holding that a skilled artisan would have had a reasonable expectation of success in characterizing the crystalline rifaximin in

the prior art for potential polymorphism using routine, conventional methods and skill, and that the rifaximin polymorph patents-in-suit were invalid as obvious. *See Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024).

156. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Amneal requests a declaration from the Court that the asserted claims of the '763 patent are invalid.

FOURTEENTH COUNTERCLAIM
(Declaratory Judgment of Non-infringement of the '763 Patent)

157. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-156 as if fully set forth herein.

158. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix regarding whether Amneal's submission of ANDA No. 218862 and/or Amneal's manufacture, use, offer to sell, sale, and/or importation into the United States of the Amneal ANDA product has infringed or will infringe any valid and enforceable claim of the '763 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

159. Amneal has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '763 patent, either literally or under the doctrine of equivalents, and is not liable for such alleged infringement at least because the claims of the '763 patent are invalid at least for the reasons provided in Amneal's confidential Notice Letter.

160. Amneal is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '763 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of the

Amneal ANDA product has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '763 patent.

FIFTEENTH COUNTERCLAIM
(Declaratory Judgment Requiring Delisting the '196 Patent)

161. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-160 as if fully set forth herein.

162. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix over the listing of the '196 patent in the Orange Book.

163. Under 21 C.F.R. § 314.53(c), only patents claiming a drug product, drug substance, or method of using the drug may be listed in the Orange Book.

164. Upon crystallization, rifaximin may take the form of one of several crystalline structures. The various polymorphs of rifaximin include Polymorph α (alpha), Polymorph β (beta), Polymorph γ (gamma), Polymorph δ (delta), and Polymorph ε (epsilon). Different polymorphs, even of the same molecule, like rifaximin, may impart different physical and chemical properties compared to one another. On information and belief, Salix's rifaximin tablets, 550 mg, which it sells under the trade name Xifaxan®, consists of Polymorph α (alpha). The claims of the '196 patent, however, are directed solely to Polymorph δ (delta) and Polymorph ε (epsilon) structures. Therefore, the '196 patent does not cover Xifaxan®, which consists of rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the Orange Book.

165. The '196 patent does not claim a drug product, drug substance, or method of using the drug as required by 21 C.F.R. § 314.53(c), and thus should be removed from the Orange Book.

166. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Salix to remove the '196 patent from the Orange Book.

SIXTEENTH COUNTERCLAIM
(Declaratory Judgment Requiring Delisting the '949 Patent)

167. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-166 as if fully set forth herein.

168. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix over the listing of the '949 patent in the Orange Book.

169. Under 21 C.F.R. § 314.53(c), only patents claiming a drug product, drug substance, or method of using the drug may be listed in the Orange Book.

170. Upon crystallization, rifaximin may take the form of one of several crystalline structures. The various polymorphs of rifaximin include Polymorph α (alpha), Polymorph β (beta), Polymorph γ (gamma), Polymorph δ (delta), and Polymorph ε (epsilon). Different polymorphs, even of the same molecule, like rifaximin, may impart different physical and chemical properties compared to one another. On information and belief, Salix's rifaximin tablets, 550 mg, which it sells under the trade name Xifaxan®, consists of Polymorph α (alpha). The claims of the '949 patent, however, are directed solely to Polymorph δ (delta) and Polymorph ε (epsilon) structures. Therefore, the'949 patent does not cover Xifaxan®, which consists of rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the Orange Book.

171. The '949 patent does not claim a drug product, drug substance, or method of using the drug as required by 21 C.F.R. § 314.53(c), and thus should be removed from the Orange Book.

172. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Salix to remove the ’949 patent from the Orange Book.

SEVENTEENTH COUNTERCLAIM
(Declaratory Judgment Requiring Delisting the ’904 Patent)

173. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-172 as if fully set forth herein.

174. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix over the listing of the ’904 patent in the Orange Book.

175. Under 21 C.F.R. § 314.53(c), only patents claiming a drug product, drug substance, or method of using the drug may be listed in the Orange Book.

176. Upon crystallization, rifaximin may take the form of one of several crystalline structures. The various polymorphs of rifaximin include Polymorph α (alpha), Polymorph β (beta), Polymorph γ (gamma), Polymorph δ (delta), and Polymorph ε (epsilon). Different polymorphs, even of the same molecule, like rifaximin, may impart different physical and chemical properties compared to one another. On information and belief, Salix’s rifaximin tablets, 550 mg, which it sells under the trade name Xifaxan®, consists of Polymorph α (alpha). The claims of the ’904 patent, however, are directed solely to Polymorph δ (delta) and Polymorph ε (epsilon) structures. Therefore, the’904 patent does not cover Xifaxan®, which consists of rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the Orange Book.

177. The ’904 patent does not claim a drug product, drug substance, or method of using the drug as required by 21 C.F.R. § 314.53(c), and thus should be removed from the Orange Book.

178. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Salix to remove the ’904 patent from the Orange Book.

EIGHTEENTH COUNTERCLAIM
(Declaratory Judgment Requiring Delisting the ’968 Patent)

179. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-178 as if fully set forth herein.

180. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix over the listing of the ’968 patent in the Orange Book.

181. Under 21 C.F.R. § 314.53(c), only patents claiming a drug product, drug substance, or method of using the drug may be listed in the Orange Book.

182. Upon crystallization, rifaximin may take the form of one of several crystalline structures. The various polymorphs of rifaximin include: Polymorph α (alpha), Polymorph β (beta), Polymorph γ (gamma), Polymorph δ (delta), and Polymorph ε (epsilon). Different polymorphs, even of the same molecule, like rifaximin, may impart different physical and chemical properties compared to one another. On information and belief, Salix’s rifaximin tablets, 550 mg, which it sells under the trade name Xifaxan®, consists of Polymorph α (alpha). The’968 patent, however, describes and refers solely to Polymorph δ (delta) and Polymorph ε (epsilon) structures. Therefore, the ’968 patent does not cover Xifaxan®, which consists of rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the Orange Book.

183. The ’968 patent does not claim a drug product, drug substance, or method of using the drug as required by 21 C.F.R. § 314.53(c), and thus should be removed from the Orange Book.

184. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Salix to remove the ’968 patent from the Orange Book.

NINETEENTH COUNTERCLAIM
(Declaratory Judgment Requiring Delisting the ’763 Patent)

185. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-184 as if fully set forth herein.

186. There is an actual, substantial, continuing, and justiciable controversy between Amneal and Salix over the listing of the ’763 patent in the Orange Book.

187. Under 21 C.F.R. § 314.53(c), only patents claiming a drug product, drug substance, or method of using the drug may be listed in the Orange Book.

188. Upon crystallization, rifaximin may take the form of one of several crystalline structures. The various polymorphs of rifaximin include: Polymorph α (alpha), Polymorph β (beta), Polymorph γ (gamma), Polymorph δ (delta), and Polymorph ε (epsilon). Different polymorphs, even of the same molecule, like rifaximin, may impart different physical and chemical properties compared to one another. On information and belief, Salix’s rifaximin tablets, 550 mg, which it sells under the trade name Xifaxan®, consists of Polymorph α (alpha). The claims of the ’763 patent, however, are directed solely to Polymorph δ (delta) and Polymorph ε (epsilon) structures. Therefore, the ’763 patent does not cover Xifaxan®, which consists of rifaximin-α, or a method of using Xifaxan®, and should not have been listed in the Orange Book.

189. The ’763 patent does not claim a drug product, drug substance, or method of using the drug as required by 21 C.F.R. § 314.53(c), and thus should be removed from the Orange Book.

190. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Salix to remove the '763 patent from the Orange Book.

TWENTIETH COUNTERCLAIM
(Unlawful Monopolization – Overall Scheme in Violation of the Sherman Act)

191. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-190 as if fully set forth herein.

192. This claim arises under the Sherman Act, 15 U.S.C. § 2 and under the Clayton Act, 15 U.S.C. §§ 15 and 26.

193. Salix is engaged in the development, commercialization, and/or marketing of prescription pharmaceutical products for the treatment of various disorders, including Xifaxan® (rifaximin), 550 mg tablets.

194. Amneal is a manufacturer and supplier of, among other things, generic pharmaceutical products.

195. Amneal is a potential future direct competitor of Salix in the Relevant Market.

196. Salix has monopoly power in the Relevant Market.

197. Salix has exercised monopoly power in the Relevant Market.

198. Salix has the power to control prices and/or exclude competition in, or prevent entry into, the Relevant Market.

199. Substantial barriers to entry into the Relevant Market exist, including but not limited to, regulatory requirements and Salix's actions to delay and preclude entry into the Relevant Market, including but not limited to, improperly listing the Asserted Polymorph Patents in the Orange Book, and Salix's present lawsuit for infringement of the Asserted Patents.

200. Salix knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by

delaying market entry of the Amneal ANDA Product. Salix baselessly and improperly wielded the Asserted Patents, including by improperly listing the Asserted Polymorph Patents in the Orange Book and asserting them in this case and others that they knew were by any objective standard invalid as obvious to trigger the automatic 30-month stay of FDA approval of Amneal's ANDA Product seeking approval to market a generic version of Xifaxan®.

201. These judicial proceedings are not a genuine effort by Salix to obtain an adjudication of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose of such action is to directly interfere with and harm Amneal's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Amneal.

202. Salix engaged in this anticompetitive scheme in order to consolidate, entrench, and enhance its monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

203. Salix's scheme and actions have no procompetitive, business justification.

204. The patent infringement claims that Salix asserted in this lawsuit against Amneal are objectively baseless. No reasonable litigant could expect to secure favorable relief against Amneal on the merits because Amneal's ANDA Product does not infringe any of the claims of the Asserted Patents, and the Asserted Patents are invalid. First, the Asserted Polymorph Patents claim rifaximin polymorphs δ (delta) and ε (epsilon). Amneal's ANDA product is rifaximin polymorph α (alpha) and therefore does not infringe those patents. Additionally, in a recent Federal Circuit decision, related Salix polymorph patents were found invalid as obvious on the grounds that there would have been a motivation to explore potential polymorphic forms of rifaximin and that it would have been well within the abilities of a skilled artisan to procure and

characterize all the polymorphs of rifaximin. *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024). Second, the Asserted IBS-D Patents consist of method of treatment claims that are nearly identical in scope to related patent claims that have been invalidated as obvious by the Federal Circuit. *See id*. at 1064.

205. Salix brought their patent infringement claims in bad faith, for an improper purpose, as a means of directly interfering with and harming Amneal's business, and to forestall, frustrate, and prevent competition by Amneal.

206. Salix intentionally engaged in the exclusionary conduct alleged herein with the express purpose of achieving and maintaining monopoly power in the Relevant Market. Salix's lawsuit filed against Amneal alleging infringement of the Asserted Patents is both objectively and subjectively baseless, and constitutes sham litigation and bad faith enforcement of the Asserted Patents.

207. Salix's anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Amneal's foreclosure from the Relevant Market and delay in entering the Relevant Market.

208. But for Salix's actions alleged herein, Salix's market share in the Relevant Market would have decreased with the addition of Amneal in the Relevant Market, to the benefit of competition and consumers in the Relevant Market.

209. On information and belief, Salix has not acted to advance their position by competing on the merits in the Relevant Market, but solely to exclude potential competition from an alternate source in the Relevant Market.

210. The effects of Salix's overall scheme, course of conduct and attempt to monopolize will be to unreasonably restrain trade and commerce in the Relevant Market, and

permit Salix to monopolize the Relevant Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, including the following effects, among others:

a. A delay of competition in the manufacture and sale of a generic equivalent of Xifaxan®;

b. Purchasers of Xifaxan® will be deprived of the benefits of free and open competition;

c. Payers and consumers will pay supracompetitive prices for Xifaxan®; and

d. Amneal will be deprived of revenues and profits it otherwise would have achieved but for Salix's illegal conduct.

211. Salix's exclusionary, anticompetitive, and unlawful activities threaten loss or damage to Amneal by forestalling, frustrating, and preventing Amneal's ability to compete in the Relevant Market.

212. As a result of Salix's exclusionary, anticompetitive, and unlawful actions, Amneal has suffered, and will continue to suffer, injury to its business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

213. The threatened injury to Amneal results from the anticompetitive nature of Salix's conduct and constitutes antitrust injury.

214. Salix's conduct occurred in, and has had a substantial effect on, interstate commerce.

215. Amneal is entitled to a judgment that Salix violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

TWENTY FIRST COUNTERCLAIM
(Unlawful Monopolization – Sham Litigation in Violation of the Sherman Act)

216. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-215 as if fully set forth herein.

217. Salix has monopoly power in the Relevant Market.

218. Salix knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of Amneal's generic equivalent of Xifaxan®. Salix has engaged in a predatory scheme to monopolize the Relevant Market through, but not limited to, initiating objectively baseless and sham judicial proceedings designed to effectuate its monopoly over sales of Xifaxan® in the United States.

219. These judicial proceedings are not a genuine effort by Salix to obtain an adjudication of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose of such action is to directly interfere with and harm Amneal's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Amneal.

220. Salix engaged in this conduct in order to consolidate, entrench, and enhance its monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

221. Salix's anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Amneal's foreclosure from the Relevant Market and delay in entering the Relevant Market.

222. As a result of Salix's exclusionary, anticompetitive, and unlawful actions, Amneal has suffered, and will continue to suffer, injury to its business and property, including lost profits

and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

223. The threatened injury to Amneal results from the anticompetitive nature of Salix's conduct and constitutes antitrust injury.

224. Salix's conduct occurred in, and has had a substantial effect on, interstate commerce.

225. Amneal is entitled to a judgment that Salix violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

TWENTY SECOND COUNTERCLAIM
(Unlawful Monopolization – Improper Orange Book Listing in Violation of the Sherman Act)

226. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-225 as if fully set forth herein.

227. Salix has monopoly power in the Relevant Market.

228. Salix knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of Amneal's generic equivalent of Xifaxan®. Salix has engaged in a predatory scheme to monopolize the Relevant Market through, but not limited to, improperly listing the Asserted Polymorph Patents in the Orange Book.

229. Salix engaged in this conduct in order to consolidate, entrench, and enhance its monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

230. Salix's anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Amneal's foreclosure from the Relevant Market and delay in entering the Relevant Market.

231. As a result of Salix's exclusionary, anticompetitive, and unlawful actions, Amneal has suffered, and will continue to suffer, injury to its business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

232. The threatened injury to Amneal results from the anticompetitive nature of Salix's conduct and constitutes antitrust injury.

233. Salix's conduct occurred in, and has had a substantial effect on, interstate commerce.

234. Amneal is entitled to a judgment that Salix has violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

TWENTY THIRD COUNTERCLAIM
(Attempted Unlawful Monopolization in Violation of the Sherman Act)

235. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-234 as if fully set forth herein.

236. Salix's scheme constitutes anticompetitive conduct taken with the specific intent to monopolize the market for Xifaxan® and its generic equivalents in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. On information and belief, Salix purposefully and knowingly improperly listed the Asserted Polymorph Patents in the Orange Book. Thereafter, Salix engaged in this sham patent litigation against Amneal under 35 U.S.C. § 271(e), despite fully knowing: (i)

the Asserted Polymorph Patents were improperly listed in the Orange Book, (ii) the Asserted Polymorph Patents were invalid as obvious in view of the holdings of *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1066 (Fed. Cir. 2024); and (iii) the Asserted IBS-D Patents were invalid as obvious in view of same, thereby unlawfully procuring an automatic 30-month stay of FDA approval. *See id*. at 1064.

237. Salix has created a dangerous probability that it will achieve its goal of monopolizing the Relevant Market. Salix's market share in the Relevant Market, coupled with other market structure and conduct evidence, including but not limited to, the lack of competition in the Relevant Market, the likely effect of competitive entry, the nature of the anticompetitive conduct alleged herein, and the related economic and market factors, constitute a dangerous probability that Salix will succeed in their efforts to maintain a monopoly in the Relevant Market.

TWENTY FOURTH COUNTERCLAIM
(Sham Litigation – Monopolization N.J. Stat. Ann. §§ 56:9-1 *et seq.*)

238. Amneal repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaim Paragraphs 1-237 as if fully set forth herein.

239. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9 *et seq*., and seeks a judgment that Salix's conduct as alleged herein violated New Jersey Antitrust, N.J. Stat. Ann. § 56:9-4. Salix's conduct as alleged herein constitutes monopolization, attempted monopolization, and maintenance of monopoly in violation of N.J. Stat. Ann. § 56:9-4.

240. Specifically, Salix's anticompetitive scheme, including abuse of the regulatory processes and court filings and improperly listing the Asserted Polymorph Patents in the Orange Book were calculated to maintain monopoly power in the Relevant Market, in violation of N.J. Stat. Ann. § 56:9-4.

241. Salix's anticompetitive and exclusionary conduct has directly and proximately caused injury to Amneal's business and property, as set forth above. Amneal's injury is of the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

PRAYER FOR RELIEF

WHEREFORE, Amneal respectfully requests judgment and relief in its favor against Salix as follows:

1. Dismissing the Salix's FAC with prejudice and denying each and every prayer for relief contained therein;

2. Declaring that the manufacture, use, sale, offer for sale, marketing, or importation of Amneal's ANDA product described in ANDA No. 218862 does not and will not infringe any valid claims of the counterclaim patents-in-suit;

3. Declaring that the asserted claims of the counterclaim patents-in-suit are invalid;

4. Declaring that the '196, '949, '904, '968, and '763 patents be delisted from the Orange Book, and therefore cannot form the basis for any 30-month stay of FDA approval of Amneal's ANDA product;

5. Enjoining Salix, their officers, employees, agents, representatives, attorneys, and others acting on its behalf, from threatening or initiating infringement litigation against Amneal or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Amneal, or charging it either orally or in writing with infringement of the counterclaim patents-in-suit;

6. Declaring that this is an exceptional case, under 35 U.S.C. § 285 and awarding Amneal its costs, expenses, and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon;

7. Declaring that Amneal is entitled to a judgment that Salix has violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees;

8. Declaring that Amneal is entitled to a judgment that Salix has violated New Jersey Antitrust, N.J. Stat. Ann. § 56:9-4; to the damages it suffered as a result of that violation, plus interest; and to its costs and attorneys' fees; and

9. Awarding to Amneal such further relief as this Court may deem necessary, just, and proper.

JURY DEMAND

Amneal demands a trial by jury on all issues for which a trial by jury is available under applicable law.

Respectfully submitted,

Date: June 18, 2024

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