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Bausch Health Ireland Ltd. and Alfasigma S.p.A.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SALIX PHARMACEUTICALS, LTD., SALIX PHARMACEUTICALS, INC., BAUSCH HEALTH IRELAND LTD., AND ALFASIGMA S.P.A.,	)	
Plaintiffs,	)	Civil Action No. 2:19-cv-18566
v.	)	
SANDOZ INC.,	)	
Defendant.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc. (collectively, "Salix"), Bausch Health Ireland Ltd. ("Bausch"), and Alfasigma S.p.A. ("Alfasigma")

(collectively, "Plaintiffs") for their First Amended Complaint against Defendant Sandoz Inc. ("Sandoz"), hereby allege as follows:

THE PARTIES

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

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

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

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

5. On information and belief, Sandoz is a corporation organized and existing under the laws of Colorado, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

6. On information and belief, Sandoz is in the business of, among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. On information and belief, this Court has personal jurisdiction over Sandoz, under the New Jersey state long arm statue and consistent with due process of law, by virtue of the fact that, *inter alia*, it maintains a principal place of business within this Judicial District at 100 College Road West, Princeton, New Jersey 08540. Sandoz has previously admitted that it has a principal place of business in New Jersey. *See, e.g.*, *Celgene Corp. v. Sandoz Inc.*, Civil Action No. 3:18-11026 (D.N.J. Sept. 25, 2018), ECF No. 18 at ¶ 3; *Genentech, Inc. et a. v. Sandoz Inc., et al.*, Civil Action No. 1:17-13507 (D.N.J. Jan. 19, 2018), ECF No. 12 at ¶ 12.

9. On information and belief, Sandoz is subject to personal jurisdiction in New Jersey because it regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, demonstrating that Sandoz has systemic and continuous contacts with this Judicial District.

10. On information and belief, Sandoz purposefully has conducted and continues to conduct business in this Judicial District by manufacturing, importing, marketing, and distributing pharmaceutical products, including generic products, either by itself or through its parent corporation, subsidiaries, and/or affiliates, throughout the United States, including in this Judicial District.

11. On information and belief, Sandoz is registered to do business in the State of New Jersey under Entity Identification Number 0100097265, and Sandoz is also licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration Number 5003732).

12. On information and belief, Sandoz is subject to personal jurisdiction in this Judicial District through its Abbreviated New Drug Application ("ANDA") No. 213713 to the

United States Food and Drug Administration ("FDA") seeking regulatory approval to manufacture, use, or sell rifaximin 550 mg tablets ("Sandoz's ANDA Product"), if approved, in this Judicial District and to residents of this Judicial District. Through at least these activities, Sandoz has purposefully availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this Judicial District.

13. On information and belief, this Court also has personal jurisdiction over Sandoz by virtue of the fact that Sandoz has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc. having commercial headquarters in the State of New Jersey. Sandoz has been, and continues to be, wholly responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 213713. Sandoz's "Notice of Paragraph IV Certification" dated September 4, 2019 identified "Sandoz Inc." as the entity which submitted ANDA No. 213713 and the entity which seeks FDA approval of ANDA No. 213713 prior to expiration of Plaintiffs' patents, and was sent to Salix's commercial headquarters at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. Plaintiffs' cause of action arose from Sandoz's contact with Salix in Bridgewater, New Jersey.

14. On information and belief, if ANDA No. 213713 is approved, Sandoz will import, market, distribute, offer for sale, and/or sell Sandoz's ANDA Product, either by itself or through its parent corporation, subsidiaries and/or affiliates, in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in the state of New Jersey.

15. On information and belief, if ANDA No. 213713 is approved, Sandoz's ANDA Product will be marketed, distributed, offered for sale, and/or sold in New Jersey; prescribed by physicians practicing in New Jersey; administered by healthcare professionals located within New Jersey; and/or used by patients in New Jersey, all of which will have a substantial effect on New Jersey.

16. On information and belief, venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because Sandoz has committed an act of infringement in New Jersey and Sandoz has a regular and established place of business in New Jersey. In addition to the acts of infringement set forth above, on information and belief, Sandoz submitted ANDA No 213713 in New Jersey and sent the Sandoz Notice Letter to one of the Plaintiffs in New Jersey. And, as set forth above, on information and belief, Sandoz Inc. maintains regular and established places of business in New Jersey, including offices, laboratories, and/or facilities at 100 College Road West, Princeton, New Jersey 08540 and One Health Plaza, Bldg. 435, East Hanover, New Jersey 07936.

NATURE OF THE ACTION

17. This is an action for infringement of United States Patent Nos. 7,045,620 (the "'620 patent"); 7,612,199 (the "'199 patent"); 7,902,206 (the "'206 patent"); 7,906,542 (the "'542 patent"); 7,915,275 (the "'275 patent"); 8,158,644 (the "'644 patent"); 8,158,781 (the "'781 patent"); 8,193,196 (the "'196 patent"); 8,309,569 (the "'569 patent"); 8,518,949 (the "'949 patent"); 8,741,904 (the "'904 patent"); 8,835,452 (the "'452 patent"); 8,853,231 (the "'231 patent"); 9,271,968 (the "'968 patent"); and 10,456,384 (the "'384 patent") (collectively, the "Xifaxan® patents") under the Food and Drug Laws and the Patent Laws of the United States, Titles 21 and 35 of the United States code, respectively. This action involves the 550 mg

dosage form of Plaintiffs' drug product Xifaxan®, indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults and treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

THE XIFAXAN® NDA

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

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

THE PATENTS-IN-SUIT

20. On May 16, 2006, the '620 patent, entitled "Polymorphous forms of rifaximin, processes for their production and use thereof in medicinal preparations," was duly and legally issued. The '620 patent is assigned to and owned by Alfasigma. A true and correct copy of the '620 patent is attached hereto as Exhibit A.

21. On November 3, 2009, the '199 patent, entitled "Polymorphic forms α, β, and γ of rifaximin," was duly and legally issued. The '199 patent is assigned to and owned by Alfasigma. A true and correct copy of the '199 patent is attached hereto as Exhibit B.

22. On March 8, 2011, the '206 patent, entitled "Polymorphic forms α, β and γ of rifaximin," was duly and legally issued. The '206 patent is assigned to and owned by Alfasigma. A true and correct copy of the '206 patent is attached hereto as Exhibit C.

23. On March 15, 2011, the ’542 patent, entitled “Pharmaceutical compositions comprising polymorphic forms α, β, and γ of rifaximin,” was duly and legally issued. The ’542 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’542 patent is attached hereto as Exhibit D.

24. On March 29, 2011, the ’275 patent, entitled “Use of polymorphic forms of rifaximin for medical preparations,” was duly and legally issued. The ’275 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’275 patent is attached hereto as Exhibit E.

25. On April 17, 2012, the ’644 patent, entitled “Pharmaceutical compositions comprising polymorphic forms α, β, and γ of rifaximin,” was duly and legally issued. The ’644 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’644 patent is attached hereto as Exhibit F.

26. On April 17, 2012, the ’781 patent, entitled “Polymorphic forms α, β and γ of rifaximin,” was duly and legally issued. The ’781 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’781 patent is attached hereto as Exhibit G.

27. On June 5, 2012, the ’196 patent, entitled “Polymorphous forms of rifaximin, processes for their production and use thereof in the medicinal preparations,” was duly and legally issued. The ’196 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’196 patent is attached hereto as Exhibit H.

28. On November 13, 2012, the ’569 patent, entitled “Methods for treating diarrhea-associated irritable bowel syndrome,” was duly and legally issued. The ’569 patent is assigned to and owned by Salix Pharmaceuticals, Ltd. A true and correct copy of the ’569 patent is attached hereto as Exhibit I.

29. On August 27, 2013, the ’949 patent, entitled “Polymorphous forms of rifaximin, processes for their production and use thereof in the medicinal preparations,” was duly and legally issued. The ’949 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’949 patent is attached hereto as Exhibit J.

30. On June 3, 2014, the ’904 patent, entitled “Polymorphous forms of rifaximin, processes for their production and use thereof in the medicinal preparations,” was duly and legally issued. The ’904 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’904 patent is attached hereto as Exhibit K.

31. On September 16, 2014, the ’452 patent, entitled “Polymorphic forms α, β and γ of rifaximin,” was duly and legally issued. The ’452 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’452 patent is attached hereto as Exhibit L.

32. On October 7, 2014, the ’231 patent, entitled “Pharmaceutical compositions comprising polymorphic forms α, β, and γ of rifaximin,” was duly and legally issued. The ’231 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’231 patent is attached hereto as Exhibit M.

33. On March 1, 2016, the ’968 patent, entitled “Polymorphous forms of rifaximin, processes for their production and use thereof in the medicinal preparations,” was duly and legally issued. The ’968 patent is assigned to and owned by Alfasigma. A true and correct copy of the ’968 patent is attached hereto as Exhibit N.

34. On October 29, 2019, the ’384 patent, entitled “Methods for treating irritable bowel syndrome,” was duly and legally issued. The ’384 patent is assigned to and owned by Salix Pharmaceuticals, Inc. A true and correct copy of the ’384 patent is attached hereto as Exhibit O.

35. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, and in conjunction with NDA No. 022554, the Xifaxan® patents are listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") for Xifaxan® 550 mg tablets.

36. Pursuant to an agreements entered into between Bausch, Salix Pharmaceuticals, Ltd., and Salix Pharmaceuticals, Inc., Bausch has substantial rights in the '569 and '384 patents, including but not limited to, an exclusive license to the '569 and '384 patents in the United States, and the right to sue for infringement of the '569 and '384 patents in the United States.

37. Pursuant to agreements entered into between Bausch, Salix Pharmaceuticals, Inc. and Alfasigma, Bausch and Salix Pharmaceuticals, Inc. have substantial rights in the '620, '199, '206, '542, '275, '644, '781, '196, '949, '904, '452, '231, and '968 patents (collectively, the "Alfasigma patents"), including but not limited to, an exclusive license to the Alfasigma patents in the United States, and the right to sue for infringement of the Alfasigma patents in the United States. Pursuant to these agreements, Salix Pharmaceuticals, Inc. is the sole distributor in the United States of Xifaxan® tablets.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

38. By a letter dated September 4, 2019 (the "Sandoz Notice Letter"), Sandoz advised Plaintiffs that it had submitted ANDA No. 213713 to the FDA seeking approval to manufacture, use, or sell Sandoz's ANDA Product prior to the expiration of the Xifaxan® patents.

39. On information and belief, Sandoz submitted ANDA No. 213713 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, and sale of Sandoz's ANDA Product as a generic version of Xifaxan® 550 mg tablets.

40. On information and belief, ANDA No. 213713 seeks FDA approval of Sandoz's ANDA Product for the indication of treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

41. The Sandoz Notice Letter also advised Plaintiffs that Sandoz's ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(B)(iv)(II) that, in Sandoz's opinion, certain claims of the Xifaxan® patents are invalid, unenforceable, and/or not infringed.

42. The Sandoz Notice Letter does not allege non-infringement of certain claims of the '199, '206, '542, '644, '781, '196, '949, '904, '452, '231, and '968 patents. By not identifying non-infringement defenses of certain claims of the '199, '206, '542, '644, '781, '196, '949, '904, '452, '231, and '968 patents in the Sandoz Notice Letter, Sandoz admits Sandoz's ANDA Product meets all limitations of those claims.

43. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and Sandoz regarding the infringement, validity, and enforceability of the Xifaxan® patents.

COUNT I
Infringement of the '620 Patent

44. Plaintiffs incorporate each of the preceding paragraphs 1 to 42 as if fully set forth herein.

45. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product throughout the United States, including New Jersey, prior to expiration of the '620 patent, Sandoz committed an act of infringement of the '620 patent under 35 U.S.C. § 271(e)(2)(A).

46. The '620 patent claims, *inter alia*, crystalline forms of rifaximin and processes for the production of crystalline forms of rifaximin.

47. Sandoz's manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product prior to the expiration of the '620 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '620 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

48. On information and belief, Sandoz was aware of the existence of the '620 patent and its listing in the Orange Book as demonstrated by Sandoz's reference to the '620 patent in the Sandoz Notice Letter.

49. On information and belief, Sandoz's statement of the factual and legal bases for its opinions regarding non-infringement of the '620 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

50. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

Count II
Infringement of the '199 Patent

51. Plaintiffs incorporate each of the preceding paragraphs 1 to 49 as if fully set forth herein.

52. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product throughout the United States, including New Jersey, prior to expiration of the '199 patent, Sandoz committed an act of infringement of the '199 patent under 35 U.S.C. § 271(e)(2)(A).

53. The '199 patent claims, *inter alia*, crystalline forms of rifaximin.

54. Sandoz's manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product prior to the expiration of the '199 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '199 patent under 35 U.S.C. § 271(a).

55. On information and belief, Sandoz was aware of the existence of the '199 patent and its listing in the Orange Book as demonstrated by Sandoz's reference to the '199 patent in the Sandoz Notice Letter.

56. On information and belief, Sandoz's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '199 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

57. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT III
Infringement of the '206 Patent

58. Plaintiffs incorporate each of the preceding paragraphs 1 to 56 as if fully set forth herein.

59. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product throughout the United States, including New Jersey, prior to expiration of the '206 patent, Sandoz committed an act of infringement of the '206 patent under 35 U.S.C. § 271(e)(2)(A).

60. The ’206 patent claims, *inter alia*, crystalline forms of rifaximin, crystalline forms of rifaximin prepared by specified processes, and solid pharmaceutical compositions comprising crystalline forms of rifaximin.

61. Sandoz’s manufacture, use, sale, offer for sale, or importation into the United States of Sandoz’s ANDA Product prior to the expiration of the ’206 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’206 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

62. On information and belief, Sandoz was aware of the existence of the ’206 patent and its listing in the Orange Book as demonstrated by Sandoz’s reference to the ’206 patent in the Sandoz Notice Letter.

63. On information and belief, Sandoz’s statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’206 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

64. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV
Infringement of the ’542 Patent

65. Plaintiffs incorporate each of the preceding paragraphs 1 to 63 as if fully set forth herein.

66. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product throughout the United States, including

New Jersey, prior to expiration of the '542 patent, Sandoz committed an act of infringement of the '542 patent under 35 U.S.C. § 271(e)(2)(A).

67. The '542 patent claims, *inter alia*, pharmaceutical compositions comprising crystalline forms of rifaximin.

68. Sandoz's manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product prior to the expiration of the '542 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '542 patent under 35 U.S.C. § 271(a).

69. On information and belief, Sandoz was aware of the existence of the '542 patent and its listing in the Orange Book as demonstrated by Sandoz's reference to the '542 patent in the Sandoz Notice Letter.

70. On information and belief, Sandoz's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '542 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

71. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT V
Infringement of the '275 Patent

72. Plaintiffs incorporate each of the preceding paragraphs 1 to 70 as if fully set forth herein.

73. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product throughout the United States, including

New Jersey, prior to expiration of the ’275 patent, Sandoz committed an act of infringement of the ’275 patent under 35 U.S.C. § 271(e)(2)(A).

74. The ’275 patent claims, *inter alia*, methods of treating bacterial infections in patients suffering from bowel related disorders with crystalline forms of rifaximin.

75. Sandoz’s manufacture, use, sale, offer for sale, or importation into the United States of Sandoz’s ANDA Product prior to the expiration of the ’275 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’275 patent under 35 U.S.C. §§ 271(b) and/or (c).

76. On information and belief, Sandoz’s ANDA Product, if approved by the FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the ’275 patent.

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

78. On information and belief, Sandoz will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs’ rights under the ’275 patent.

79. On information and belief, Sandoz knows or should know Sandoz’s ANDA Product will be especially made or especially adapted for use in an infringement of the ’275 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

80. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the '275 patent's expiry will contribute to the direct infringement of one or more claims of the '275 patent.

81. On information and belief, Sandoz's acts will be performed with knowledge of the '275 patent and with intent to encourage infringement prior to the '275 patent's expiry. This case is exceptional.

82. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT VI
Infringement of the '644 Patent

83. Plaintiffs incorporate each of the preceding paragraphs 1 to 81 as if fully set forth herein.

84. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product throughout the United States, including New Jersey, prior to expiration of the '644 patent, Sandoz committed an act of infringement of the '644 patent under 35 U.S.C. § 271(e)(2)(A).

85. The '644 patent claims, *inter alia*, solid pharmaceutical compositions comprising crystalline forms of rifaximin.

86. Sandoz's manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product prior to the expiration of the '644 patent, including

any applicable exclusivities or extensions, will infringe one or more claims of the '644 patent under 35 U.S.C. § 271(a).

87. On information and belief, Sandoz was aware of the existence of the '644 patent and its listing in the Orange Book as demonstrated by Sandoz's reference to the '644 patent in the Sandoz Notice Letter.

88. On information and belief, Sandoz's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '644 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

89. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT VII
Infringement of the '781 Patent

90. Plaintiffs incorporate each of the preceding paragraphs 1 to 88 as if fully set forth herein.

91. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product throughout the United States, including New Jersey, prior to expiration of the '781 patent, Sandoz committed an act of infringement of the '781 patent under 35 U.S.C. § 271(e)(2)(A).

92. The '781 patent claims, *inter alia*, crystalline forms of rifaximin.

93. Sandoz's manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product prior to the expiration of the '781 patent, including

any applicable exclusivities or extensions, will infringe one or more claims of the '781 patent under 35 U.S.C. § 271(a).

94. On information and belief, Sandoz was aware of the existence of the '781 patent and its listing in the Orange Book as demonstrated by Sandoz's reference to the '781 patent in the Sandoz Notice Letter.

95. On information and belief, Sandoz's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '781 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

96. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT VIII
Infringement of the '196 Patent

97. Plaintiffs incorporate each of the preceding paragraphs 1 to 95 as if fully set forth herein.

98. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product throughout the United States, including New Jersey, prior to expiration of the '196 patent, Sandoz committed an act of infringement of the '196 patent under 35 U.S.C. § 271(e)(2)(A).

99. The '196 patent claims, *inter alia*, crystalline forms of rifaximin, solid pharmaceutical compositions comprising crystalline forms of rifaximin, methods of treating bacterial activity in the gastrointestinal tract of subjects with crystalline forms of rifaximin, and processes for the production of crystalline forms of rifaximin.

100. Sandoz's manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product prior to the expiration of the '196 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '196 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

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

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

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

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

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

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

107. On information and belief, Sandoz was aware of the existence of the '196 patent and its listing in the Orange Book as demonstrated by Sandoz's reference to the '196 patent in the Sandoz Notice Letter.

108. On information and belief, Sandoz's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '196 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

109. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IX
Infringement of the '569 Patent

110. Plaintiffs incorporate each of the preceding paragraphs 1 to 108 as if fully set forth herein.

111. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product throughout the United States, including New Jersey, prior to expiration of the '569 patent, Sandoz committed an act of infringement of the '569 patent under 35 U.S.C. § 271(e)(2)(A).

112. The '569 patent claims, *inter alia*, methods of treating diarrhea-associated irritable bowel syndrome with rifaximin.

113. Sandoz's manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product prior to the expiration of the '569 patent, including

any applicable exclusivities or extensions, will infringe one or more claims of the ’569 patent under 35 U.S.C. §§ 271(b) and/or (c).

114. On information and belief, Sandoz’s ANDA Product, if approved by the FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the ’569 patent.

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

116. On information and belief, Sandoz will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs’ rights under the ’569 patent.

117. On information and belief, Sandoz knows or should know Sandoz’s ANDA Product will be especially made or especially adapted for use in an infringement of the ’569 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

118. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product prior to the ’569 patent’s expiry will contribute to the direct infringement of one or more claims of the ’569 patent.

119. On information and belief, Sandoz’s acts will be performed with knowledge of the ’569 patent and with intent to encourage infringement prior to the ’569 patent’s expiry.

120. On information and belief, Sandoz was aware of the existence of the ’569 patent and its listing in the Orange Book as demonstrated by Sandoz’s reference to the ’569 patent in the Sandoz Notice Letter.

121. On information and belief, Sandoz’s statement of the factual and legal bases for its opinions regarding invalidity of the ’569 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

122. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT X
Infringement of the ’949 Patent

123. Plaintiffs incorporate each of the preceding paragraphs 1 to 121 as if fully set forth herein.

124. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product throughout the United States, including New Jersey, prior to expiration of the ’949 patent, Sandoz committed an act of infringement of the ’949 patent under 35 U.S.C. § 271(e)(2)(A).

125. The ’949 patent claims, *inter alia*, solid pharmaceutical compositions comprising crystalline forms of rifaximin and crystalline forms of rifaximin prepared by specified processes.

126. Sandoz’s manufacture, use, sale, offer for sale, or importation into the United States of Sandoz’s ANDA Product prior to the expiration of the ’949 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’949 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

127. On information and belief, Sandoz was aware of the existence of the ’949 patent and its listing in the Orange Book as demonstrated by Sandoz’s reference to the ’949 patent in the Sandoz Notice Letter.

128. On information and belief, Sandoz’s statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’949 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

129. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT XI
Infringement of the ’904 Patent

130. Plaintiffs incorporate each of the preceding paragraphs 1 to 128 as if fully set forth herein.

131. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product throughout the United States, including New Jersey, prior to expiration of the ’904 patent, Sandoz committed an act of infringement of the ’904 patent under 35 U.S.C. § 271(e)(2)(A).

132. The ’904 patent claims, *inter alia*, crystalline forms of rifaximin, methods of treating bacterial activity in the gastrointestinal tract of subjects with crystalline forms of rifaximin, and medicinal preparations comprising crystalline forms of rifaximin.

133. Sandoz’s manufacture, use, sale, offer for sale, or importation into the United States of Sandoz’s ANDA Product prior to the expiration of the ’904 patent, including

any applicable exclusivities or extensions, will infringe one or more claims of the '904 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

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

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

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

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

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

140. On information and belief, Sandoz was aware of the existence of the ’904 patent and its listing in the Orange Book as demonstrated by Sandoz’s reference to the ’904 patent in the Sandoz Notice Letter.

141. On information and belief, Sandoz’s statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’904 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

142. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT XII
Infringement of the ’452 Patent

143. Plaintiffs incorporate each of the preceding paragraphs 1 to 141 as if fully set forth herein.

144. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product throughout the United States, including New Jersey, prior to expiration of the ’452 patent, Sandoz committed an act of infringement of the ’452 patent under 35 U.S.C. § 271(e)(2)(A).

145. The ’452 patent claims, *inter alia*, crystalline forms of rifaximin and pharmaceutical compositions comprising crystalline forms of rifaximin.

146. Sandoz’s manufacture, use, sale, offer for sale, or importation into the United States of Sandoz’s ANDA Product prior to the expiration of the ’452 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’452 patent under 35 U.S.C. § 271(a).

147. On information and belief, Sandoz was aware of the existence of the ’452 patent and its listing in the Orange Book as demonstrated by Sandoz’s reference to the ’452 patent in the Sandoz Notice Letter.

148. On information and belief, Sandoz’s statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’452 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

149. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT XIII
Infringement of the ’231 Patent

150. Plaintiffs incorporate each of the preceding paragraphs 1 to 148 as if fully set forth herein.

151. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product throughout the United States, including New Jersey, prior to expiration of the ’231 patent, Sandoz committed an act of infringement of the ’231 patent under 35 U.S.C. § 271(e)(2)(A).

152. The ’231 patent claims, *inter alia*, pharmaceutical compositions comprising crystalline forms of rifaximin.

153. Sandoz’s manufacture, use, sale, offer for sale, or importation into the United States of Sandoz’s ANDA Product prior to the expiration of the ’231 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’231 patent under 35 U.S.C. § 271(a).

154. On information and belief, Sandoz was aware of the existence of the ’231 patent and its listing in the Orange Book as demonstrated by Sandoz’s reference to the ’231 patent in the Sandoz Notice Letter.

155. On information and belief, Sandoz’s statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’231 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

156. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT XIV
Infringement of the ’968 Patent

157. Plaintiffs incorporate each of the preceding paragraphs 1 to 155 as if fully set forth herein.

158. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product throughout the United States, including New Jersey, prior to expiration of the ’968 patent, Sandoz committed an act of infringement of the ’968 patent under 35 U.S.C. § 271(e)(2)(A).

159. The ’968 patent claims, *inter alia*, pharmaceutical compositions comprising crystalline forms of rifaximin.

160. Sandoz’s manufacture, use, sale, offer for sale, or importation into the United States of Sandoz’s ANDA Product prior to the expiration of the ’968 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’968 patent under 35 U.S.C. § 271(a).

161. On information and belief, Sandoz was aware of the existence of the ’968 patent and its listing in the Orange Book as demonstrated by Sandoz’s reference to the ’968 patent in the Sandoz Notice Letter.

162. On information and belief, Sandoz’s statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’968 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

163. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT XV
Infringement of the ’384 Patent

164. Plaintiffs incorporate each of the preceding paragraphs 1 to 163 as if fully set forth herein.

165. By submitting ANDA No. 213713 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product throughout the United States, including New Jersey, prior to expiration of the ’384 patent, Sandoz committed an act of infringement of the ’384 patent under 35 U.S.C. § 271(e)(2)(A).

166. The ’384 patent claims, *inter alia*, methods of treating irritable bowel syndrome in subjects 65 years of age or older with rifaximin.

167. Sandoz’s manufacture, use, sale, offer for sale, or importation into the United States of Sandoz’s ANDA Product prior to the expiration of the ’384 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’384 patent under 35 U.S.C. §§ 271(b) and/or (c).

168. The ’384 patent issued after the Sandoz Notice Letter was sent.

169. The ’384 patent was listed in the Orange Book on or about November 12, 2019.

170. On information and belief, Sandoz was aware of the ’384 patent prior to the filing date of this First Amended Complaint.

171. On information and belief, Sandoz’s ANDA Product, if approved by the FDA, will be prescribed and administered to human patients to relieve the signs and symptoms of irritable bowel syndrome in patients 65 years of age or older, in the amount of 550 mg three times a day for 14 days, which uses will constitute direct infringement of claims of the ’384 patent.

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

173. On information and belief, Sandoz will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs’ rights under the ’384 patent.

174. On information and belief, Sandoz knows or should know Sandoz’s ANDA Product will be especially made or especially adapted for use in an infringement of the ’384 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

175. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product prior to the ’384 patent’s expiry will contribute to the direct infringement of one or more claims of the ’384 patent.

176. On information and belief, Sandoz's acts will be performed with knowledge of the '384 patent and with intent to encourage infringement prior to the '384 patent's expiry. This case is exceptional.

177. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Sandoz has infringed one or more claims of United States Patent Nos. 7,045,620; 7,612,199; 7,902,206; 7,906,542; 7,915,275; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,741,904; 8,835,452; 8,853,231; 9,271,968; and 10,456,384 by submitting ANDA No. 213713 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the Xifaxan® patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Sandoz's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Sandoz's ANDA Product will infringe one or more claims of United States Patent Nos. 7,045,620; 7,612,199; 7,902,206; 7,906,542; 7,915,275; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,741,904; 8,835,452; 8,853,231; 9,271,968; and 10,456,384 under 35 U.S.C. §§ 271(a), (b), (c), and/or (g);

C. A judgment that United States Patent Nos. 7,045,620; 7,612,199; 7,902,206; 7,906,542; 7,915,275; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,741,904; 8,835,452; 8,853,231; 9,271,968; and 10,456,384 remain valid and enforceable;

D. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Sandoz, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Sandoz's ANDA Product prior to the expiration date of United States Patent Nos. 7,045,620; 7,612,199; 7,902,206; 7,906,542; 7,915,275; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,741,904; 8,835,452; 8,853,231; 9,271,968; and 10,456,384, inclusive of any exclusivities and extensions;

E. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 213713 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of United States Patent Nos. 7,045,620; 7,612,199; 7,902,206; 7,906,542; 7,915,275; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,741,904; 8,835,452; 8,853,231; 9,271,968; and 10,456,384 inclusive of any exclusivities and extensions;

F. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

G. Costs and expenses in this action; and

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

Dated: December 16, 2019

Respectfully submitted,

s/ Charles H Chevalier____
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** was caused to be served on the following persons by email on December 16, 2019:

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s/ Charles H. Chevalier
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