IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, LTD.; SALIX PHARMACEUTICALS, INC.; VALEANT PHARMACEUTICALS LUXEMBOURG S.À R.L.; ALFA WASSERMANN S.P.A.; CEDARS-SINAI MEDICAL CENTER,	)	
Plaintiffs,	)	
	)	Civil Action No.: 16-cv-188-GMS
v.	)	
ACTAVIS LABORATORIES FL, INC.,	)	
Defendant.	)	

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc. (collectively, "Salix"), Valeant Pharmaceuticals Luxembourg S.à r.l. ("Valeant"), Alfa Wassermann S.p.A. ("Alfa Wassermann"), and Cedars-Sinai Medical Center ("Cedars-Sinai") (collectively, "Plaintiffs") for their Second Amended Complaint against Defendant Actavis Laboratories FL, Inc. ("Actavis"), 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 8510 Colonnade Center Drive, Raleigh, NC 27615.

2. Plaintiff Salix Pharmaceuticals, Inc. is a corporation organized and existing under the laws of California having its principal place of business at 8510 Colonnade Center Drive, Raleigh, NC 27615.

3. Plaintiff Valeant is a company organized and existing under the laws of Luxembourg having its principal place of business at 13-15 Avenue de la Liberté, L-1931 Luxembourg, Grand Duchy of Luxembourg.

4. Plaintiff Alfa Wassermann is a corporation organized and existing under the laws of Italy having a principal place of business at Via Enrico Fermi 1, 65020 Alanno (PE), Italy.

5. Plaintiff Cedars-Sinai is a California non-profit, public benefit corporation that is located and does business at 8700 Beverly Blvd., Los Angeles, CA 90048.

6. On information and belief, Actavis is a corporation organized and existing under the laws of Florida, having a place of business at 4955 Orange Drive, Davie, FL 33314.

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

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over Actavis by virtue of the fact that, *inter alia*, it has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of Delaware, and throughout the United States.

10. This Court also has personal jurisdiction over Actavis by virtue of the fact that Actavis has previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction. *See, e.g., Recro Gainesville LLC v. Actavis Laboratories FL, Inc.*, C.A. No. 14-

cv-1118-GMS, D.I. 75 (D. Del. Jan. 14, 2016); *Cosmo Tech. Ltd. et al. v. Actavis Laboratories FL, Inc.*, C.A. No. 15-cv-1046-LPS, D.I. 9 (D. Del. Dec. 7, 2015); *Purdue Pharma L.P. et al. v. Alvogen Pine Brook, LLC and Actavis Laboratories FL, Inc.*, C.A. No. 15-cv-687-GMS, D.I. 27 (D. Del. Nov. 30, 2015); *Takeda Pharm. Co. et al. v. Actavis Laboratories FL, Inc.*, C.A. No. 15-cv-451-RGA, D.I. 11 (D. Del. July 27, 2015); *Acorda Therapeutics, Inc. et al. v. Actavis Laboratories FL, Inc.*, C.A. No. 15-cv-77-LPS, D.I. 7 (D. Del. Feb. 17, 2015); *Tris Pharma, Inc. v. Actavis Laboratories FL, Inc.*, C.A. No. 14-cv-1309-GMS, D.I. 16 (D. Del. Dec. 5, 2014); and *Daravita Ltd. v. Actavis Laboratories FL, Inc.*, C.A. No. 14-cv-1118-GMS, D.I. 14 (D. Del. Oct. 24, 2014).

11. This Court also has personal jurisdiction over Actavis by virtue of the fact that Actavis is at home in Delaware as reflected by the fact that it regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Actavis conducts marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

NATURE OF THE ACTION

13. This is an action for infringement of United States Patent Nos. 6,861,053 (the "'053 patent"); 7,045,620 (the "'620 patent"); 7,452,857 (the "'857 patent"); 7,605,240 (the "'240 patent"); 7,612,199 (the "'199 patent"); 7,718,608 (the "'608 patent"); 7,902,206 (the "'206 patent"); 7,906,542 (the "'542 patent"); 7,915,275 (the "'275 patent"); 7,935,799 (the "'799 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"); 8,642,573 (the "'573 patent"); 8,741,904 (the "'904 patent"); 8,829,017 (the "'017 patent"); 8,835,452 (the "'452 patent"); 8,853,231 (the "'231 patent"); 8,946,252 (the "'252 patent"); 8,969,398 (the "'398 patent"); 9,271,968 (the "'968 patent") and 9,421,195 (the "'195 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

14. 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) tablets.

15. The United States Food and Drug Administration ("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

16. On March 1, 2005, the ’053 patent, entitled “Methods of diagnosing or treating irritable bowel syndrome and other disorders caused by small intestinal bacterial overgrowth,” was duly and legally issued to Cedars-Sinai. A true and correct copy of the ’053 patent is attached hereto as Exhibit A.

17. 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 to Alfa Wassermann. A true and correct copy of the ’620 patent is attached hereto as Exhibit B.

18. On November 18, 2008, the ’857 patent, entitled “Methods of treating irritable bowel syndrome and other disorders caused by small intestinal bacterial overgrowth,” was duly and legally issued to Cedars-Sinai. A true and correct copy of the ’857 patent is attached hereto as Exhibit C.

19. On October 20, 2009, the ’240 patent, entitled “Methods of treating diarrhea and bloating caused by small intestinal bacterial overgrowth,” was duly and legally issued to Cedars-Sinai. A true and correct copy of the ’240 patent is attached hereto as Exhibit D.

20. On November 3, 2009, the ’199 patent, entitled “Polymorphic forms α, β, and γ of rifaximin,” was duly and legally issued to Alfa Wassermann. A true and correct copy of the ’199 patent is attached hereto as Exhibit E.

21. On May 18, 2010, the ’608 patent, entitled “Methods of treating a subject suffering from irritable bowel syndrome,” was duly and legally issued to Cedars-Sinai. A true and correct copy of the ’608 patent is attached hereto as Exhibit F.

22. On March 8, 2011, the ’206 patent, entitled “Polymorphic forms α, β and γ of rifaximin,” was duly and legally issued to Alfa Wassermann. A true and correct copy of the ’206 patent is attached hereto as Exhibit G.

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 to Alfa Wassermann. A true and correct copy of the ’542 patent is attached hereto as Exhibit H.

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

25. On May 3, 2011, the ’799 patent, entitled “Methods of treating diarrhea caused by small intestinal bacterial overgrowth,” was duly and legally issued to Cedars-Sinai. A true and correct copy of the ’799 patent is attached hereto as Exhibit J.

26. On April 17, 2012, the ’644 patent, entitled “Pharmaceutical compositions comprising polymorphic forms α, β, and γ of rifaximin,” was duly and legally issued to Alfa Wassermann. A true and correct copy of the ’644 patent is attached hereto as Exhibit K.

27. On April 17, 2012, the ’781 patent, entitled “Polymorphic forms α, β and γ of rifaximin,” was duly and legally issued to Alfa Wassermann. A true and correct copy of the ’781 patent is attached hereto as Exhibit L.

28. 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 to Alfa Wassermann. A true and correct copy of the ’196 patent is attached hereto as Exhibit M.

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

30. 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 to Alfa Wassermann. A true and correct copy of the ’949 patent is attached hereto as Exhibit O.

31. On February 4, 2014, the ’573 patent, entitled “Methods of treating hepatic encephalopathy,” was duly and legally issued to Salix Pharmaceuticals, Ltd. A true and correct copy of the ’573 patent is attached hereto as Exhibit P.

32. 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 to Alfa Wassermann. A true and correct copy of the ’904 patent is attached hereto as Exhibit Q.

33. On September 9, 2014, the ’017 patent, entitled “Methods of treating traveler’s diarrhea and hepatic encephalopathy,” was duly and legally issued to Salix Pharmaceuticals, Ltd. A true and correct copy of the ’017 patent is attached hereto as Exhibit R.

34. On September 16, 2014, the ’452 patent, entitled “Polymorphic forms α, β and γ of rifaximin,” was duly and legally issued to Alfa Wassermann. A true and correct copy of the ’452 patent is attached hereto as Exhibit S.

35. On October 7, 2014, the ’231 patent, entitled “Pharmaceutical compositions comprising polymorphic forms α, β, and γ of rifaximin,” was duly and legally issued to Alfa Wassermann. A true and correct copy of the ’231 patent is attached hereto as Exhibit T.

36. On February 3, 2015, the ’252 patent, entitled “Methods of treating traveler’s diarrhea and hepatic encephalopathy,” was duly and legally issued to Salix Pharmaceuticals, Ltd. A true and correct copy of the ’252 patent is attached hereto as Exhibit U.

37. On March 3, 2015, the ’398 patent, entitled “Methods of treating hepatic encephalopathy,” was duly and legally issued to Salix Pharmaceuticals, Ltd. A true and correct copy of the ’398 patent is attached hereto as Exhibit V.

38. 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 to Alfa Wassermann. A true and correct copy of the ’968 patent is attached hereto as Exhibit W.

39. On August 23, 2016, the ’195 patent, entitled “Methods of Treating Hepatic Encephalopathy,” was duly and legally issued to Salix Pharmaceuticals, Ltd. A true and correct copy of the ’195 patent is attached hereto as Exhibit X.

40. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, 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.

41. Pursuant to an agreement entered into between Valeant and Salix Pharmaceuticals, Ltd., Valeant has substantial rights in the ’569, ’573, ’017, ’252,’398 and ’195 patents (collectively, the “Salix patents”), including but not limited to, rights associated with

being the exclusive licensee of the Salix patents in the United States, and the right to sue for infringement of the Salix patents in the United States.

42. Pursuant to agreements entered into between Valeant, Salix Pharmaceuticals, Inc. and Alfa Wassermann, Valeant 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 “Alfa Wassermann patents”), including but not limited to, rights associated with being the exclusive licensee of the Alfa Wassermann patents in the United States, and the right to sue for infringement of the Alfa Wassermann patents in the United States. Pursuant to these agreements, Salix Pharmaceuticals, Inc. is the sole distributor in the United States of Xifaxan® tablets.

43. Pursuant to agreements entered into between Valeant, Salix Pharmaceuticals, Inc. and Cedars-Sinai, Valeant and Salix Pharmaceuticals, Inc. have substantial rights in the ’053, ’857, ’240, ’608, and ’799 patents (collectively, the “Cedars-Sinai patents”), including but not limited to, rights associated with being the exclusive licensee of the Cedars-Sinai patents, and the right to sue for infringement of the Cedars-Sinai patents.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

44. By a letter dated February 11, 2016 (the “Actavis Notice Letter”), Actavis advised Salix Pharmaceuticals, Inc., Alfa Wassermann and Cedars-Sinai, that it had submitted ANDA No. 208959 to the FDA seeking approval to manufacture, use, or sell rifaximin 550 mg tablets (“Actavis’ Generic Product”) prior to the expiration of the Xifaxan® patents.

45. On information and belief, Actavis submitted ANDA No. 208959 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 Actavis' Generic Product as a generic version of Xifaxan® 550 mg tablets.

46. On information and belief, ANDA No. 208959 seeks FDA approval of Actavis' Generic Product for the indications of reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults and treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

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

48. The Actavis Notice Letter does not allege non-infringement of certain claims of the '199, '608, '206, '542, '275, '644, '781, '196, '569, '949, '904, '452, and '231 patents. By not identifying non-infringement defenses of certain claims of the '199, '608, '206, '542, '275, '644, '781, '196, '569, '949, '904, '452, and '231 patents in the Actavis Notice Letter, Actavis admits Actavis' Generic Product meets all limitations of those claims.

49. The Actavis Notice Letter does not allege invalidity or unenforceability of any claims of the '620, '799, and '398 patents, and does not allege invalidity or unenforceability of certain claims of the '053, '199, '206, '542, '644, '781, '196, and '231 patents. By not identifying invalidity and unenforceability defenses of any claims of the '620, '799, and '398 patents in the Actavis Notice Letter, Actavis admits the claims of those patents are valid and enforceable. By not identifying invalidity and unenforceability defenses of certain claims of the '053, '199, '206, '542, '644, '781, '196, and '231 patents in the Actavis Notice Letter, Actavis admits those claims of those patents are valid and enforceable.

50. By letter dated July 6, 2016, (the "Second Actavis Notice Letter"), Actavis advised Salix Pharmaceuticals, Inc., Alfa Wassermann and Cedars-Sinai, that it had amended

ANDA No. 208959 to include a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Actavis' opinion, the claims of the '968 patent are invalid, unenforceable and/or not infringed.

51. The Second Actavis Notice Letter does not allege non-infringement of any claims of the '968 patent. By not identifying non-infringement defenses of any claims of the '968 patent in the Second Actavis Notice Letter, Actavis admits Actavis' Generic Produce meets all limitations of those claims.

52. By a letter dated October 31, 2016 (the "Third Actavis Notice Letter"), Actavis advised Salix Pharmaceuticals, Inc., Alfa Wassermann and Cedars-Sinai, that it had amended ANDA No. 208959 to include a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Actavis' opinion, the claims of the '195 patent are invalid, unenforceable and/or not infringed.

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

COUNT I
Infringement of the '053 Patent

54. Plaintiffs incorporate each of the preceding paragraphs 1 to 53 as if fully set forth herein.

55. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '053 patent, Actavis committed an act of infringement of the '053 patent under 35 U.S.C. § 271(e)(2)(A).

56. The '053 patent claims, *inter alia*, methods of treating irritable bowel syndrome with rifaximin.

57. Actavis' manufacture, use, sale, offer for sale, or importation into the United

States of Actavis' Generic Product prior to the expiration of the '053 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '053 patent under 35 U.S.C. §§ 271(b) and/or (c).

58. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the '053 patent.

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

60. On information and belief, Actavis 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 '053 patent.

61. On information and belief, Actavis knows or should know Actavis' Generic Product will be especially made or especially adapted for use in an infringement of the '053 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

62. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '053 patent.

63. On information and belief, Actavis' acts will be performed with knowledge of the '053 patent and with intent to encourage infringement prior to patent expiry.

64. On information and belief, Actavis was aware of the existence of the ’053 patent and its listing in the Orange Book as demonstrated by Actavis’ reference to the ’053 patent in the Actavis Notice Letter.

65. On information and belief, Actavis’ statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’053 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

66. 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 ’620 Patent

67. Plaintiffs incorporate each of the preceding paragraphs 1 to 66 as if fully set forth herein.

68. By submitting ANDA No. 208959 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 Actavis’ Generic Product throughout the United States, including Delaware, prior to expiration of the ’620 patent, Actavis committed an act of infringement of the ’620 patent under 35 U.S.C. § 271(e)(2)(A).

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

70. Actavis’ manufacture, use, sale, offer for sale, or importation into the United States of Actavis’ Generic 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).

71. On information and belief, Actavis was aware of the existence of the ’620 patent and its listing in the Orange Book as demonstrated by Actavis’ reference to the ’620 patent in the Actavis Notice Letter.

72. On information and belief, Actavis’ 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.

73. 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 ’857 Patent

74. Plaintiffs incorporate each of the preceding paragraphs 1 to 73 as if fully set forth herein.

75. By submitting ANDA No. 208959 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 Actavis’ Generic Product throughout the United States, including Delaware, prior to expiration of the ’857 patent, Actavis committed an act of infringement of the ’857 patent under 35 U.S.C. § 271(e)(2)(A).

76. The ’857 patent claims, *inter alia*, methods of treating irritable bowel syndrome with rifaximin.

77. Actavis’ manufacture, use, sale, offer for sale, or importation into the United States of Actavis’ Generic Product prior to the expiration of the ’857 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’857 patent under 35 U.S.C. §§ 271(b) and/or (c).

78. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the '857 patent.

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

80. On information and belief, Actavis 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 '857 patent.

81. On information and belief, Actavis knows or should know Actavis' Generic Product will be especially made or especially adapted for use in an infringement of the '857 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

82. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '857 patent.

83. On information and belief, Actavis' acts will be performed with knowledge of the '857 patent and with intent to encourage infringement prior to patent expiry.

84. On information and belief, Actavis was aware of the existence of the '857 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '857 patent in the Actavis Notice Letter.

85. On information and belief, Actavis' statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '857 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

86. 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 '240 Patent

87. Plaintiffs incorporate each of the preceding paragraphs 1 to 86 as if fully set forth herein.

88. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '240 patent, Actavis committed an act of infringement of the '240 patent under 35 U.S.C. § 271(e)(2)(A).

89. The '240 patent claims, *inter alia*, methods of treating bloating with rifaximin.

90. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic Product prior to the expiration of the '240 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '240 patent under 35 U.S.C. §§ 271(b) and/or (c).

91. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the '240

patent.

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

93. On information and belief, Actavis 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 '240 patent.

94. On information and belief, Actavis knows or should know Actavis' Generic Product will be especially made or especially adapted for use in an infringement of the '240 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

95. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '240 patent.

96. On information and belief, Actavis' acts will be performed with knowledge of the '240 patent and with intent to encourage infringement prior to patent expiry.

97. On information and belief, Actavis was aware of the existence of the '240 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '240 patent in the Actavis Notice Letter.

98. On information and belief, Actavis' statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '240 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

99. 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 '199 Patent

100. Plaintiffs incorporate each of the preceding paragraphs 1 to 99 as if fully set forth herein.

101. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '199 patent, Actavis committed an act of infringement of the '199 patent under 35 U.S.C. § 271(e)(2)(A).

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

103. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic 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).

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

105. On information and belief, Actavis' 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.

106. 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 '608 Patent

107. Plaintiffs incorporate each of the preceding paragraphs 1 to 106 as if fully set forth herein.

108. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '608 patent, Actavis committed an act of infringement of the '608 patent under 35 U.S.C. § 271(e)(2)(A).

109. The '608 patent claims, *inter alia*, methods of treating subjects suffering from irritable bowel syndrome with rifaximin and methods of improving the symptoms of a subject suffering from irritable bowel syndrome with rifaximin.

110. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic Product prior to the expiration of the '608 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '608 patent under 35 U.S.C. §§ 271(b) and/or (c).

111. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the '608 patent.

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

113. On information and belief, Actavis 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 '608 patent.

114. On information and belief, Actavis knows or should know Actavis' Generic Product will be especially made or especially adapted for use in an infringement of the '608 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

115. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '608 patent.

116. On information and belief, Actavis' acts will be performed with knowledge of the '608 patent and with intent to encourage infringement prior to patent expiry.

117. On information and belief, Actavis was aware of the existence of the '608 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '608 patent in the Actavis Notice Letter.

118. On information and belief, Actavis' statement of the factual and legal bases for its opinions regarding invalidity of the '608 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

119. 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 ’206 Patent

120. Plaintiffs incorporate each of the preceding paragraphs 1 to 119 as if fully set forth herein.

121. By submitting ANDA No. 208959 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 Actavis’ Generic Product throughout the United States, including Delaware, prior to expiration of the ’206 patent, Actavis committed an act of infringement of the ’206 patent under 35 U.S.C. § 271(e)(2)(A).

122. 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.

123. Actavis’ manufacture, use, sale, offer for sale, or importation into the United States of Actavis’ Generic 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).

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

125. On information and belief, Actavis’ 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.

126. 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 '542 Patent

127. Plaintiffs incorporate each of the preceding paragraphs 1 to 126 as if fully set forth herein.

128. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '542 patent, Actavis committed an act of infringement of the '542 patent under 35 U.S.C. § 271(e)(2)(A).

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

130. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic 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).

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

132. On information and belief, Actavis' 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.

133. 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 '275 Patent

134. Plaintiffs incorporate each of the preceding paragraphs 1 to 133 as if fully set forth herein.

135. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '275 patent, Actavis committed an act of infringement of the '275 patent under 35 U.S.C. § 271(e)(2)(A).

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

137. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic 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).

138. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or 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.

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

140. On information and belief, Actavis 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.

141. On information and belief, Actavis knows or should know Actavis' Generic 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.

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

143. On information and belief, Actavis' acts will be performed with knowledge of the '275 patent and with intent to encourage infringement prior to patent expiry.

144. On information and belief, Actavis was aware of the existence of the '275 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '275 patent in the Actavis Notice Letter.

145. On information and belief, Actavis' statement of the factual and legal bases for its opinions regarding invalidity of the '275 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

146. 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 '799 Patent

147. Plaintiffs incorporate each of the preceding paragraphs 1 to 146 as if fully set forth herein.

148. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '799 patent, Actavis committed an act of infringement of the '799 patent under 35 U.S.C. § 271(e)(2)(A).

149. The '799 patent claims, *inter alia*, methods of treating diarrhea in subjects who have small intestinal bacterial overgrowth with rifaximin.

150. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic Product prior to the expiration of the '799 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '799 patent under 35 U.S.C. §§ 271(b) and/or (c).

151. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the '799 patent.

152. On information and belief, these directly infringing uses will occur with Actavis'

specific intent and encouragement, and will be uses that Actavis knows or should know will occur.

153. On information and belief, Actavis 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 '799 patent.

154. On information and belief, Actavis knows or should know Actavis' Generic Product will be especially made or especially adapted for use in an infringement of the '799 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

155. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '799 patent.

156. On information and belief, Actavis' acts will be performed with knowledge of the '799 patent and with intent to encourage infringement prior to patent expiry.

157. On information and belief, Actavis was aware of the existence of the '799 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '799 patent in the Actavis Notice Letter.

158. On information and belief, Actavis' statement of the factual and legal bases for its opinions regarding non-infringement of the '799 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

159. 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 ’644 Patent

160. Plaintiffs incorporate each of the preceding paragraphs 1 to 159 as if fully set forth herein.

161. By submitting ANDA No. 208959 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 Actavis’ Generic Product throughout the United States, including Delaware, prior to expiration of the ’644 patent, Actavis committed an act of infringement of the ’644 patent under 35 U.S.C. § 271(e)(2)(A).

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

163. Actavis’ manufacture, use, sale, offer for sale, or importation into the United States of Actavis’ Generic 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).

164. On information and belief, Actavis was aware of the existence of the ’644 patent and its listing in the Orange Book as demonstrated by Actavis’ reference to the ’644 patent in the Actavis Notice Letter.

165. On information and belief, Actavis’ 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.

166. 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 ’781 Patent

167. Plaintiffs incorporate each of the preceding paragraphs 1 to 166 as if fully set forth herein.

168. By submitting ANDA No. 208959 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 Actavis’ Generic Product throughout the United States, including Delaware, prior to expiration of the ’781 patent, Actavis committed an act of infringement of the ’781 patent under 35 U.S.C. § 271(e)(2)(A).

169. The ’781 patent claims, *inter alia*, crystalline forms of rifaximin.

170. Actavis’ manufacture, use, sale, offer for sale, or importation into the United States of Actavis’ Generic 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).

171. On information and belief, Actavis was aware of the existence of the ’781 patent and its listing in the Orange Book as demonstrated by Actavis’ reference to the ’781 patent in the Actavis Notice Letter.

172. On information and belief, Actavis’ 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.

173. 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 ’196 Patent

174. Plaintiffs incorporate each of the preceding paragraphs 1 to 173 as if fully set forth herein.

175. By submitting ANDA No. 208959 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 Actavis’ Generic Product throughout the United States, including Delaware, prior to expiration of the ’196 patent, Actavis committed an act of infringement of the ’196 patent under 35 U.S.C. § 271(e)(2)(A).

176. 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.

177. Actavis’ manufacture, use, sale, offer for sale, or importation into the United States of Actavis’ Generic 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).

178. On information and belief, Actavis’ Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or 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.

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

occur.

180. On information and belief, Actavis 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.

181. On information and belief, Actavis knows or should know Actavis' Generic 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.

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

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

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

185. On information and belief, Actavis' 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.

186. 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 ’569 Patent

187. Plaintiffs incorporate each of the preceding paragraphs 1 to 186 as if fully set forth herein.

188. By submitting ANDA No. 208959 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 Actavis’ Generic Product throughout the United States, including Delaware, prior to expiration of the ’569 patent, Actavis committed an act of infringement of the ’569 patent under 35 U.S.C. § 271(e)(2)(A).

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

190. Actavis’ manufacture, use, sale, offer for sale, or importation into the United States of Actavis’ Generic 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).

191. On information and belief, Actavis’ Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or 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.

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

193. On information and belief, Actavis 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.

194. On information and belief, Actavis knows or should know Actavis' Generic 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.

195. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '569 patent.

196. On information and belief, Actavis' acts will be performed with knowledge of the '569 patent and with intent to encourage infringement prior to patent expiry.

197. On information and belief, Actavis was aware of the existence of the '569 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '569 patent in the Actavis Notice Letter.

198. On information and belief, Actavis' 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.

199. 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 '949 Patent

200. Plaintiffs incorporate each of the preceding paragraphs 1 to 199 as if fully set forth herein.

201. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '949 patent, Actavis committed an act of infringement of the '949 patent under 35 U.S.C. § 271(e)(2)(A).

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

203. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic 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).

204. On information and belief, Actavis was aware of the existence of the '949 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '949 patent in the Actavis Notice Letter.

205. On information and belief, Actavis' 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.

206. 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 XVI
Infringement of the '573 Patent

207. Plaintiffs incorporate each of the preceding paragraphs 1 to 206 as if fully set forth herein.

208. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '573 patent, Actavis committed an act of infringement of the '573 patent under 35 U.S.C. § 271(e)(2)(A).

209. The '573 patent claims, *inter alia*, methods of maintaining remission of hepatic encephalopathy with rifaximin.

210. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic Product prior to the expiration of the '573 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '573 patent under 35 U.S.C. §§ 271(b) and/or (c).

211. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the '573 patent.

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

213. On information and belief, Actavis 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 '573 patent.

214. On information and belief, Actavis knows or should know Actavis' Generic

Product will be especially made or especially adapted for use in an infringement of the ’573 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

215. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis’ Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the ’573 patent.

216. On information and belief, Actavis’ acts will be performed with knowledge of the ’573 patent and with intent to encourage infringement prior to patent expiry.

217. On information and belief, Actavis was aware of the existence of the ’573 patent and its listing in the Orange Book as demonstrated by Actavis’ reference to the ’573 patent in the Actavis Notice Letter.

218. On information and belief, Actavis’ statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the ’573 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

219. 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 XVII
Infringement of the ’904 Patent

220. Plaintiffs incorporate each of the preceding paragraphs 1 to 219 as if fully set forth herein.

221. By submitting ANDA No. 208959 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 Actavis’ Generic Product throughout the United States, including

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

222. 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.

223. Actavis’ manufacture, use, sale, offer for sale, or importation into the United States of Actavis’ Generic 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).

224. On information and belief, Actavis’ Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or 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.

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

226. On information and belief, Actavis 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.

227. On information and belief, Actavis knows or should know Actavis’ Generic 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.

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

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

230. On information and belief, Actavis was aware of the existence of the '904 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '904 patent in the Actavis Notice Letter.

231. On information and belief, Actavis' 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.

232. 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 XVIII
Infringement of the '017 Patent

233. Plaintiffs incorporate each of the preceding paragraphs 1 to 232 as if fully set forth herein.

234. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '017 patent, Actavis committed an act of infringement of the '017 patent under 35 U.S.C. § 271(e)(2)(A).

235. The ’017 patent claims, *inter alia*, methods of treating patients having hepatic encephalopathy with rifaximin and methods of treating patients suffering from hepatic encephalopathy with rifaximin.

236. Actavis’ manufacture, use, sale, offer for sale, or importation into the United States of Actavis’ Generic Product prior to the expiration of the ’017 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’017 patent under 35 U.S.C. §§ 271(b) and/or (c).

237. On information and belief, Actavis’ Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the ’017 patent.

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

239. On information and belief, Actavis 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 ’017 patent.

240. On information and belief, Actavis knows or should know Actavis’ Generic Product will be especially made or especially adapted for use in an infringement of the ’017 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

241. On information and belief, Actavis knows or should know that its commercial

manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '017 patent.

242. On information and belief, Actavis' acts will be performed with knowledge of the '017 patent and with intent to encourage infringement prior to patent expiry.

243. On information and belief, Actavis was aware of the existence of the '017 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '017 patent in the Actavis Notice Letter.

244. On information and belief, Actavis' statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '017 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

245. 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 XIX
Infringement of the '452 Patent

246. Plaintiffs incorporate each of the preceding paragraphs 1 to 245 as if fully set forth herein.

247. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '452 patent, Actavis committed an act of infringement of the '452 patent under 35 U.S.C. § 271(e)(2)(A).

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

249. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic 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).

250. On information and belief, Actavis was aware of the existence of the '452 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '452 patent in the Actavis Notice Letter.

251. On information and belief, Actavis' 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.

252. 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 XX
Infringement of the '231 Patent

253. Plaintiffs incorporate each of the preceding paragraphs 1 to 252 as if fully set forth herein.

254. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '231 patent, Actavis committed an act of infringement of the '231 patent under 35 U.S.C. § 271(e)(2)(A).

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

256. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic 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).

257. On information and belief, Actavis was aware of the existence of the '231 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '231 patent in the Actavis Notice Letter.

258. On information and belief, Actavis' 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.

259. 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 XXI
Infringement of the '252 Patent

260. Plaintiffs incorporate each of the preceding paragraphs 1 to 259 as if fully set forth herein.

261. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '252 patent, Actavis committed an act of infringement of the '252 patent under 35 U.S.C. § 271(e)(2)(A).

262. The '252 patent claims, *inter alia*, methods of reducing the risk of overt hepatic encephalopathy recurrence in subjects with rifaximin.

263. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic Product prior to the expiration of the '252 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '252 patent under 35 U.S.C. §§ 271(b) and/or (c).

264. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the '252 patent.

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

266. On information and belief, Actavis 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 '252 patent.

267. On information and belief, Actavis knows or should know Actavis' Generic Product will be especially made or especially adapted for use in an infringement of the '252 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

268. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '252 patent.

269. On information and belief, Actavis' acts will be performed with knowledge of the

'252 patent and with intent to encourage infringement prior to patent expiry.

270. On information and belief, Actavis was aware of the existence of the '252 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '252 patent in the Actavis Notice Letter.

271. On information and belief, Actavis' statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '252 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

272. 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 XXII
Infringement of the '398 Patent

273. Plaintiffs incorporate each of the preceding paragraphs 1 to 272 as if fully set forth herein.

274. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '398 patent, Actavis committed an act of infringement of the '398 patent under 35 U.S.C. § 271(e)(2)(A).

275. The '398 patent claims, *inter alia*, methods of decreasing the risk of a hepatic encephalopathy breakthrough episode with rifaximin.

276. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic Product prior to the expiration of the '398 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '398 patent under

35 U.S.C. §§ 271(b) and/or (c).

277. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the '398 patent.

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

279. On information and belief, Actavis 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 '398 patent.

280. On information and belief, Actavis knows or should know Actavis' Generic Product will be especially made or especially adapted for use in an infringement of the '398 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

281. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '398 patent.

282. On information and belief, Actavis' acts will be performed with knowledge of the '398 patent and with intent to encourage infringement prior to patent expiry.

283. On information and belief, Actavis was aware of the existence of the '398 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '398 patent in the

Actavis Notice Letter.

284. On information and belief, Actavis' statement of the factual and legal bases for its opinions regarding non-infringement of the '398 patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

285. 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 XXIII
Infringement of the '968 Patent

286. Plaintiffs incorporate each of the preceding paragraphs 1 to 285 as if fully set forth herein.

287. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '968 patent, Actavis committed an act of infringement of the '968 patent under 35 U.S.C. § 271(e)(2)(A).

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

289. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic 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).

290. The '968 patent issued after the Actavis Notice Letter was sent.

291. The '968 patent was listed in the Orange Book on or about June 10, 2016.

292. The Actavis Notice Letter does not allege non-infringement of claims 7-9 of the '196 patent, claims 12-14 and 17-19 of the '949 patent, or claims 1-7 and 19-35 of the '904 patent. By not identifying non-infringement defenses of claims 7-9 of the '196 patent, claims 12-14 and 17-19 of the '949 patent, or claims 1-7 and 19-35 of the '904 patent in the Actavis Notice Letter, Actavis admits Actavis' Generic Product meets all limitations of those claims.

293. On information and belief, because of Actavis' admissions concerning the limitations of claims 7-9 of the '196 patent, claims 12-14 and 17-19 of the '949 patent, and claims 1-7 and 19-35 of the '904 patent, Actavis' Generic Product meets all limitations of the claims of the '968 patent. For example:

a. Claim 1 of the '968 patent reads as follows: A pharmaceutical composition comprising a therapeutically effective amount of rifaximin together with excipients, wherein the rifaximin has a X-ray powder diffraction pattern peaks at about 5.7°±0.2, 6.7°±0.2 and 8.0°±0.2.

b. Claim 7 of the '196 patent reads as follows: A solid pharmaceutical composition comprising a therapeutically effective amount of rifaximin δ, rifaximin ε, or a combination thereof, and a pharmaceutically acceptable excipient, together disposed in a formulation for oral administration, wherein the rifaximin δ has X-ray powder diffraction pattern peaks at about 5.7°±0.2, 10.8°±0.2, 12.1°±0.2, and 17.0°±0.2, 2-θ, and wherein the rifaximin ε has X-ray powder diffraction pattern peaks at about 8.2°±0.2, 12.4°±0.2, and 16.3°±0.2 2-θ.

c. Claim 12 of the '949 patent reads as follows: A solid pharmaceutical composition comprising a therapeutically effective amount of rifaximin δ and

a pharmaceutically acceptable excipient, together disposed in a formulation for oral administration, wherein the rifaximin polymorphic form δ has x-ray powder diffraction pattern peaks at about 5.7°±0.2, 12.1°±0.2, and 17.0°±0.2 2-θ.

d. Claim 5 of the ’904 patent reads as follows: The rifaximin in polymorphic form δ of claim 1, wherein the polymorph has x-ray powder diffraction pattern peaks at about 5.7°±0.2, 6.7°±0.2, 7.1°±0.2, 8.0°±0.2, 8.7°±0.2, 10.4°±0.2, 11.3°±0.2, 12.1°±0.2, 17.0°±0.2, 17.3°±0.2, 17.5°±0.2, 18.5°±0.2, 18.8°±0.2, 19.1°±0.2, 21.0°±0.2 and 21.5°±0.2 2-θ.

294. On information and belief, Actavis was aware of the ’968 patent prior to the filing date of the First Amended Complaint.

295. On information and belief, Actavis’ statement of the factual and legal bases for its opinions regarding non-infringement of the ’968 patent set forth in the Second Actavis Notice Letter is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

296. 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 XXIV
Infringement of the ’195 Patent

297. Plaintiffs incorporate each of the preceding paragraphs 1 to 296 as if fully set forth herein.

298. By submitting ANDA No. 208959 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 Actavis' Generic Product throughout the United States, including Delaware, prior to expiration of the '195 patent, Actavis committed an act of infringement of the '195 patent under 35 U.S.C. § 271(e)(2)(A).

299. The '195 patent claims, *inter alia*, methods of reducing the risk of hepatic encephalopathy recurrence with rifaximin.

300. Actavis' manufacture, use, sale, offer for sale, or importation into the United States of Actavis' Generic Product prior to the expiration of the '195 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '195 patent under 35 U.S.C. §§ 271(b) and/or (c).

301. The '195 patent issued after the Actavis Notice Letter and Second Actavis Notice Letter were sent.

302. The '195 patent was listed in the Orange Book on or about October 2016.

303. On information and belief, Actavis' Generic Product, if approved by the FDA, will be prescribed and administered to human patients to reduce the risk of overt hepatic encephalopathy recurrence and/or to relieve the signs and symptoms of irritable bowel syndrome with diarrhea in patients, which uses will constitute direct infringement of claims of the '195 patent.

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

305. On information and belief, Actavis 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 '195 patent.

306. On information and belief, Actavis knows or should know Actavis' Generic Product will be especially made or especially adapted for use in an infringement of the '195 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

307. On information and belief, Actavis knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product prior to patent expiry will contribute to the direct infringement of one or more claims of the '195 patent.

308. On information and belief, Actavis' acts will be performed with knowledge of the '195 patent and with intent to encourage infringement prior to patent expiry.

309. On information and belief, Actavis was aware of the existence of the '195 patent and its listing in the Orange Book as demonstrated by Actavis' reference to the '195 patent in the Third Actavis Notice Letter.

310. On information and belief, Actavis' statement of the factual and legal bases for its opinions regarding non-infringement of the '195 patent set forth in the Third Actavis Notice Letter is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

311. 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 Actavis has infringed one or more claims of United States Patent Nos. 6,861,053; 7,045,620; 7,452,857; 7,605,240; 7,612,199; 7,718,608; 7,902,206; 7,906,542;

7,915,275; 7,935,799; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,642,573; 8,741,904; 8,829,017; 8,835,452; 8,853,231; 8,946,252; 8,969,398; 9,271,968 and 9,421,195 by submitting ANDA No. 208959 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Actavis' Generic Product before the expiration of the Xifaxan® patents under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Actavis' commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Actavis' Generic Product will infringe one or more claims of United States Patent Nos. 6,861,053; 7,045,620; 7,452,857; 7,605,240; 7,612,199; 7,718,608; 7,902,206; 7,906,542; 7,915,275; 7,935,799; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,642,573; 8,741,904; 8,829,017; 8,835,452; 8,853,231; 8,946,252; 8,969,398; 9,271,968 and 9,421,195 under 35 U.S.C. §§ 271(a), (b), (c) and/or (g);

C. A judgment that United States Patent Nos. 6,861,053; 7,045,620; 7,452,857; 7,605,240; 7,612,199; 7,718,608; 7,902,206; 7,906,542; 7,915,275; 7,935,799; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,642,573; 8,741,904; 8,829,017; 8,835,452; 8,853,231; 8,946,252; 8,969,398; 9,271,968 and 9,421,195 remain valid and enforceable;

D. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Actavis, 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 Actavis' Generic Product prior to the expiration date of United States Patent Nos. 6,861,053; 7,045,620; 7,452,857; 7,605,240; 7,612,199; 7,718,608; 7,902,206; 7,906,542; 7,915,275; 7,935,799; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,642,573; 8,741,904; 8,829,017; 8,835,452; 8,853,231; 8,946,252; 8,969,398; 9,271,968 and 9,421,195, inclusive of any extensions;

E. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 208959 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. 6,861,053; 7,045,620; 7,452,857; 7,605,240; 7,612,199; 7,718,608; 7,902,206; 7,906,542; 7,915,275; 7,935,799; 8,158,644; 8,158,781; 8,193,196; 8,309,569; 8,518,949; 8,642,573; 8,741,904; 8,829,017; 8,835,452; 8,853,231; 8,946,252; 8,969,398; 9,271,968 and 9,421,195, inclusive of any 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 12, 2016

Respectfully Submitted,

/s/ Mary W. Bourke
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CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of December, 2016 I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on the following counsel of record via electronic mail:

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