Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs
Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland Limited

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, **Plaintiffs,** **v.** **WOCKHARDT BIO AG, WOCKHARDT LIMITED, and WOCKHARDT USA LLC,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz Pharmaceuticals"), by their undersigned attorneys, for their Complaint against defendants Wockhardt Bio Ag, Wockhardt Limited, and Wockhardt USA LLC (collectively, "Wockhardt"), allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Wockhardt's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Jazz Pharmaceuticals' XYREM® drug

product prior to the expiration of United States Patent Nos. 6,472,431 (the "'431 patent"), 6,780,889 (the "'889 patent"), 7,262,219 (the "'219 patent"), 7,851,506 (the "'506 patent"), 8,263,650 (the "'650 patent"), 8,324,275 (the "'275 patent"), 8,461,203 (the "'203 patent"), 7,668,730 (the "'730 patent"), 7,765,106 (the "'106 patent"), 7,765,107 (the "'107 patent"), 7,895,059 (the "'059 patent"), 8,457,988 (the "'988 patent"), 8,589,182 (the "'182 patent"), 8,731,963 (the "'963 patent"), 8,772,306 (the "'306 patent"), 8,859,619 (the "'619 patent"), and 8,952,062 (the "'062 patent") owned by Jazz Pharmaceuticals (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3180 Porter Drive, Palo Alto, California 94304.

3. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at One Burlington Road, Fourth Floor, Connaught House, Dublin, Ireland 4.

4. On information and belief, defendant Wockhardt Limited is an Indian corporation, having a principal place of business at Wockhardt Towers, Bandra Kurla Complex, Bandra (East) Mumbai – 400 051, Maharashtra, India. On information and belief, Wockhardt Limited is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Wockhardt Limited regularly conducts business in New Jersey including in this Judicial District.

5. On information and belief, defendant Wockhardt Bio Ag is a Swiss corporation, having a principal place of business at Baarerstrasse 43, 6300 ZUG, Switzerland. On information and belief, Wockhardt Bio Ag is a wholly-owned subsidiary of Wockhardt Limited.

On information and belief, Wockhardt Bio Ag is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Wockhardt Bio Ag regularly conducts business in New Jersey including in this Judicial District.

6. On information and belief, defendant Wockhardt USA LLC is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Waterview Boulevard, 3rd Floor, Parsippany, NJ 07054-1271. On information and belief, Wockhardt USA LLC is a wholly-owned subsidiary of Wockhardt Limited. On information and belief, Wockhardt USA LLC is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, and Wockhardt USA LLC regularly conducts business in New Jersey including in this Judicial District.

7. On information and belief, Defendants Wockhardt USA LLC, Wockhardt Limited, and Wockhardt Bio Ag acted collaboratively in the preparation and submission of ANDA No. 207526 to the FDA. On information and belief, Wockhardt Bio Ag's submission of ANDA No. 207526 to the FDA was done at the direction, under the control, and for the direct benefit of Wockhardt Limited.

8. On information and belief, following any FDA approval of ANDA No. 207526, Defendants Wockhardt USA LLC, Wockhardt Limited, and Wockhardt Bio Ag will work in concert with one another to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 207526 throughout the United States, and/or import such generic products into the United States.

Jurisdiction and Venue

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

10. This Court has personal jurisdiction over Defendant Wockhardt USA LLC because, *inter alia*, Wockhardt USA LLC's principal place of business is located in the State of New Jersey. Wockhardt USA LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

11. This Court has personal jurisdiction over Defendant Wockhardt Limited because, *inter alia,* Wockhardt Limited has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. On information and belief, Defendant Wockhardt Limited regularly and continuously transacts business within the State of New Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through its affiliates, including Wockhardt USA LLC. On information and belief, Wockhardt Limited derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey. Wockhardt Limited has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction

12. This Court has personal jurisdiction over Defendant Wockhardt Bio Ag because, *inter alia,* Wockhardt Bio Ag has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. On information and belief, Defendant Wockhardt Bio Ag regularly and continuously transacts business within the State of New Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through its affiliates, including Wockhardt USA LLC. On information and belief, Wockhardt Bio Ag derives substantial revenue from the sale of those products in New Jersey and

has availed itself of the privilege of conducting business within the State of New Jersey. Wockhardt Bio Ag has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions in this jurisdiction.

13. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents-In-Suit

14. On October 29, 2002, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '431 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '431 patent is attached hereto as Exhibit A.

15. On August 24, 2004, the USPTO duly and lawfully issued the '889 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '889 patent is attached hereto as Exhibit B.

16. On August 28, 2007, the USPTO duly and lawfully issued the '219 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '219 patent is attached hereto as Exhibit C.

17. On December 14, 2010, the USPTO duly and lawfully issued the '506 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '506 patent is attached hereto as Exhibit D.

18. On September 11, 2012, the USPTO duly and lawfully issued the '650 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '650 patent is attached hereto as Exhibit E.

19. On December 4, 2012, the USPTO duly and lawfully issued the ’275 patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ’275 patent is attached hereto as Exhibit F.

20. On June 11, 2013, the USPTO duly and lawfully issued the ’203 Patent, entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy.” A copy of the ’203 patent is attached hereto as Exhibit G.

21. On February 23, 2010, the USPTO duly and lawfully issued the ’730 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ’730 patent is attached hereto as Exhibit H.

22. On July 27, 2010, the USPTO duly and lawfully issued the ’106 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ’106 patent is attached hereto as Exhibit I.

23. On July 27, 2010, the USPTO duly and lawfully issued the ’107 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ’107 patent is attached hereto as Exhibit J.

24. On February 22, 2011, the USPTO duly and lawfully issued the ’059 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ’059 patent is attached hereto as Exhibit K.

25. On June 4, 2013, the USPTO duly and lawfully issued the ’988 patent, entitled “Sensitive Drug Distribution System and Method.” A copy of the ’988 patent is attached hereto as Exhibit L.

26. On November 19, 2013, the USPTO duly and lawfully issued the '182 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '182 patent is attached hereto as Exhibit M.

27. On May 20, 2014, the USPTO duly and lawfully issued the '963 patent, entitled "Sensitive Drug Distribution System and Method." A copy of the '963 patent is attached hereto as Exhibit N.

28. On July 8, 2014, the USPTO duly and lawfully issued the '306 patent, entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters." A copy of the '306 patent is attached hereto as Exhibit O.

29. On October 14, 2014, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '619 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '619 patent is attached hereto as Exhibit P.

30. On February 10, 2015, the USPTO duly and lawfully issued the '062 patent, entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy." A copy of the '062 patent is attached hereto as Exhibit Q.

The XYREM® Drug Product

31. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM®. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical compositions containing sodium oxybate, and methods of use and administration of sodium oxybate or pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patents-in-suit.

32. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, '306, '619 and '062 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM®.

33. The labeling for XYREM® instructs and encourages physicians, other healthcare workers, and patients to administer XYREM® according to the methods claimed in several of the patents-in-suit.

Acts Giving Rise to This Suit

34. Pursuant to Section 505 of the FFDCA, Wockhardt filed ANDA No. 207526 ("Wockhardt's ANDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of 500 mg/mL sodium oxybate oral solution ("Wockhardt's Proposed Product"), before the patents-in-suit expire.

35. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Wockhardt has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Wockhardt's Paragraph IV Certification"), alleging that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, '306, '619 and '062 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt's ANDA.

36. No earlier than June 8, 2015, Jazz Pharmaceuticals received written notice of Wockhardt's Paragraph IV Certification ("Wockhardt's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Wockhardt's Notice Letter alleged that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, '306, '619 and '062 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt's

ANDA. Wockhardt's Notice Letter also informed Jazz Pharmaceuticals that Wockhardt's seeks approval to market Wockhardt's Proposed Product before the patents-in-suit expire.

37. On information and belief, Wockhardt has not submitted a statement to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that Wockhardt seeks to market its Proposed Product for a use other than the uses claimed in the patents-in-suit.

38. Under applicable laws and regulations, the FDA will not approve Wockhardt's Proposed Product with labeling that does not include information regarding dose modification in patients receiving concomitant administration of sodium oxybate and valproate that is necessary for the safe and effective use of sodium oxybate.

Count I: Infringement of the '431 Patent

39. Plaintiffs repeat and reallege the allegations of paragraphs 1-38 as though fully set forth herein.

40. Wockhardt, through its submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '431 patent. Wockhardt's actions with respect to its ANDA show that there is a substantial controversy, between the parties, of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

41. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution prior to the expiration of the '431 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

42. There is a justiciable controversy between the parties hereto as to the infringement of the '431 patent.

43. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '431 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

44. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '431 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '431 patent and knowledge that its acts are encouraging infringement.

45. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '431 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '431 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

46. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '431 patent is not enjoined.

47. Jazz Pharmaceuticals does not have an adequate remedy at law.

48. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '889 Patent

49. Plaintiffs repeat and reallege the allegations of paragraphs 1-48 as though fully set forth herein.

50. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '889 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

51. There is a justiciable controversy between the parties hereto as to the infringement of the '889 patent.

52. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '889 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

53. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '889 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '889 patent and knowledge that its acts are encouraging infringement.

54. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '889 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '889 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

55. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '889 patent is not enjoined.

56. Jazz Pharmaceuticals does not have an adequate remedy at law.

57. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '219 Patent

58. Plaintiffs repeat and reallege the allegations of paragraphs 1-57 as though fully set forth herein.

59. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '219 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

60. There is a justiciable controversy between the parties hereto as to the infringement of the '219 patent.

61. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '219 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

62. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '219 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '219 patent and knowledge that its acts are encouraging infringement.

63. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '219 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United

States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '219 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

64. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '219 patent is not enjoined.

65. Jazz Pharmaceuticals does not have an adequate remedy at law.

66. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '506 Patent

67. Plaintiffs repeat and reallege the allegations of paragraphs 1-66 as though fully set forth herein.

68. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '506 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

69. There is a justiciable controversy between the parties hereto as to the infringement of the '506 patent.

70. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '506 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

71. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '506 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will

intentionally encourage acts of direct infringement with knowledge of the '506 patent and knowledge that its acts are encouraging infringement.

72. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '506 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '506 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

73. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '506 patent is not enjoined.

74. Jazz Pharmaceuticals does not have an adequate remedy at law.

75. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '650 Patent

76. Plaintiffs repeat and reallege the allegations of paragraphs 1-75 as though fully set forth herein.

77. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '650 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

78. There is a justiciable controversy between the parties hereto as to the infringement of the '650 patent.

79. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '650 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

80. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '650 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '650 patent and knowledge that its acts are encouraging infringement.

81. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '650 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '650 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

82. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '650 patent is not enjoined.

83. Jazz Pharmaceuticals does not have an adequate remedy at law.

84. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '275 Patent

85. Plaintiffs repeat and reallege the allegations of paragraphs 1-84 as though fully set forth herein.

86. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '275 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

87. There is a justiciable controversy between the parties hereto as to the infringement of the '275 patent.

88. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '275 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

89. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '275 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '275 patent and knowledge that its acts are encouraging infringement.

90. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '275 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '275 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

91. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '275 patent is not enjoined.

92. Jazz Pharmaceuticals does not have an adequate remedy at law.

93. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '203 Patent

94. Plaintiffs repeat and reallege the allegations of paragraphs 1-93 as though fully set forth herein.

95. Wockhardt, through its submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '203 patent. Wockhardt's actions with respect to its ANDA show that there is a substantial controversy, between the parties, of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

96. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution prior to the expiration of the '203 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2)(A).

97. There is a justiciable controversy between the parties hereto as to the infringement of the '203 patent.

98. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '203 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

99. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '203 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United

States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '203 patent and knowledge that its acts are encouraging infringement.

100. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '203 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '203 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

101. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '203 patent is not enjoined.

102. Jazz Pharmaceuticals does not have an adequate remedy at law.

103. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '730 Patent

104. Plaintiffs repeat and reallege the allegations of paragraphs 1-103 as though fully set forth herein.

105. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '730 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

106. There is a justiciable controversy between the parties hereto as to the infringement of the '730 patent.

107. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '730 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

108. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '730 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '730 patent and knowledge that its acts are encouraging infringement.

109. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '730 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '730 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

110. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '730 patent is not enjoined.

111. Jazz Pharmaceuticals does not have an adequate remedy at law.

112. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX: Infringement of the '106 Patent

113. Plaintiffs repeat and reallege the allegations of paragraphs 1-112 as though fully set forth herein.

114. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '106 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

115. There is a justiciable controversy between the parties hereto as to the infringement of the '106 patent.

116. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '106 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

117. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '106 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '106 patent and knowledge that its acts are encouraging infringement.

118. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '106 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '106 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

119. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '106 patent is not enjoined.

120. Jazz Pharmaceuticals does not have an adequate remedy at law.

121. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count X: Infringement of the '107 Patent

122. Plaintiffs repeat and reallege the allegations of paragraphs 1-121 as though fully set forth herein.

123. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '107 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

124. There is a justiciable controversy between the parties hereto as to the infringement of the '107 patent.

125. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '107 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

126. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '107 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '107 patent and knowledge that its acts are encouraging infringement.

127. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '107 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United

States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '107 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

128. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '107 patent is not enjoined.

129. Jazz Pharmaceuticals does not have an adequate remedy at law.

130. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XI: Infringement of the '059 Patent

131. Plaintiffs repeat and reallege the allegations of paragraphs 1-130 as though fully set forth herein.

132. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '059 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

133. There is a justiciable controversy between the parties hereto as to the infringement of the '059 patent.

134. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '059 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

135. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '059 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will

intentionally encourage acts of direct infringement with knowledge of the '059 patent and knowledge that its acts are encouraging infringement.

136. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '059 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '059 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

137. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '059 patent is not enjoined.

138. Jazz Pharmaceuticals does not have an adequate remedy at law.

139. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XII: Infringement of the '988 Patent

140. Plaintiffs repeat and reallege the allegations of paragraphs 1-139 as though fully set forth herein.

141. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '988 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

142. There is a justiciable controversy between the parties hereto as to the infringement of the '988 patent.

143. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '988 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

144. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '988 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '988 patent and knowledge that its acts are encouraging infringement.

145. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '988 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '988 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

146. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '988 patent is not enjoined.

147. Jazz Pharmaceuticals does not have an adequate remedy at law.

148. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIII: Infringement of the '182 Patent

149. Plaintiffs repeat and reallege the allegations of paragraphs 1-148 as though fully set forth herein.

150. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '182 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

151. There is a justiciable controversy between the parties hereto as to the infringement of the '182 patent.

152. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '182 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

153. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '182 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '182 patent and knowledge that its acts are encouraging infringement.

154. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '182 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '182 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

155. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '182 patent is not enjoined.

156. Jazz Pharmaceuticals does not have an adequate remedy at law.

157. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIV: Infringement of the '963 Patent

158. Plaintiffs repeat and reallege the allegations of paragraphs 1-157 as though fully set forth herein.

159. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '963 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

160. There is a justiciable controversy between the parties hereto as to the infringement of the '963 patent.

161. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '963 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

162. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '963 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '963 patent and knowledge that its acts are encouraging infringement.

163. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '963 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United

States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '963 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

164. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '963 patent is not enjoined.

165. Jazz Pharmaceuticals does not have an adequate remedy at law.

166. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XV: Infringement of the '306 Patent

167. Plaintiffs repeat and reallege the allegations of paragraphs 1-166 as though fully set forth herein.

168. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '306 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

169. There is a justiciable controversy between the parties hereto as to the infringement of the '306 patent.

170. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '306 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

171. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '306 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will

intentionally encourage acts of direct infringement with knowledge of the '306 patent and knowledge that its acts are encouraging infringement.

172. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '306 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '306 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

173. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '306 patent is not enjoined.

174. Jazz Pharmaceuticals does not have an adequate remedy at law.

175. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XVI: Infringement of the '619 Patent

176. Plaintiffs repeat and reallege the allegations of paragraphs 1-175 as though fully set forth herein.

177. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '619 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

178. There is a justiciable controversy between the parties hereto as to the infringement of the '619 patent.

179. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '619 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

180. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '619 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '619 patent and knowledge that its acts are encouraging infringement.

181. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '619 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '619 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

182. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '619 patent is not enjoined.

183. Jazz Pharmaceuticals does not have an adequate remedy at law.

184. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XVII: Infringement of the '062 Patent

185. Plaintiffs repeat and reallege the allegations of paragraphs 1-184 as though fully set forth herein.

186. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '062 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

187. There is a justiciable controversy between the parties hereto as to the infringement of the '062 patent.

188. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '062 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

189. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '062 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '062 patent and knowledge that its acts are encouraging infringement.

190. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '062 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '062 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

191. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '062 patent is not enjoined.

192. Jazz Pharmaceuticals does not have an adequate remedy at law.

193. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment be entered that Wockhardt has infringed the patents-in-suit by submitting ANDA No. 207526;

(B) A Judgment be entered that Wockhardt has infringed, and that Wockhardt's making, using, selling, offering to sell, or importing Wockhardt's Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 207526 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Wockhardt and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Wockhardt's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Wockhardt, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Wockhardt's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Wockhardt has committed any acts with respect to the compositions and methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts;

(H) If Wockhardt engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Wockhardt's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: July 17, 2015

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs
Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland Limited

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Gabriel P. Brier
Andrew S. Chalson
Frank C. Calvosa
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010

(212) 849-7000

Richard G. Greco
RICHARD G. GRECO PC
90 State Street, Suite 700
Albany, New York 12207
(212) 203-7625

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that the matters captioned *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 10-6108 (ES)(MAH), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC, et al.*, Civil Action No. 13-391 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Roxane Laboratories, Inc.*, Civil Action No. 15-1360 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, *et al.*, Civil Action No. 15-3217 (ES)(JAD), *Jazz Pharmaceuticals, Inc. et al. v. Roxane Laboratories, Inc.*, Civil Action No. 15-3684 (ES)(JAD), and *Jazz Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*, Civil Action No. 15-4532 (ES)(JAD) are related to the matter in controversy because the matter in controversy involves defendants who filed Abbreviated New Drug Applications seeking to market generic versions of the same drug product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: July 17, 2015

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs
Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland Limited

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Gabriel P. Brier
Andrew S. Chalson
Frank C. Calvosa
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010

(212) 849-7000

Richard G. Greco
RICHARD G. GRECO PC
90 State Street, Suite 700
Albany, New York 12207
(212) 203-7625