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Jazz Pharmaceuticals, Inc. and
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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, **Plaintiffs,** **v.** **LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz Pharmaceuticals" or "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, "Lupin" or "Defendants"), 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 Lupin'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"), 8,952,062 (the "'062 patent"), and 9,050,302 (the "'302 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 Lupin Ltd. is an Indian corporation organized and existing under the laws of India, having its principal place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (E), Mumbai 400 051, India, and its registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, *inter alia*, developing, manufacturing, distributing, and selling pharmaceutical products throughout the United States, including within this Judicial District, either on its own or through its affiliates, including Lupin Pharmaceuticals Inc.

5. On information and belief, Defendant Lupin Pharmaceuticals Inc. ("Lupin Inc.") is a corporation organized and existing under the laws of the Commonwealth of Virginia, having

a principal place of business at 111 South Calvert Street, Baltimore, Maryland 21202. On information and belief, Lupin Inc. is in the business of, *inter alia*, manufacturing, distributing, and selling pharmaceutical products throughout the United States, including within this district, either on its own or through its affiliates.

6. On information and belief, Lupin Inc. is a wholly owned subsidiary of Lupin Ltd.

7. On information and belief, following any FDA approval of ANDA No. 207415, Defendants Lupin Ltd. and Lupin Inc. 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. 207415 throughout the United States, and/or import such generic products into 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(a), 2201, and 2202.

9. On information and belief, Lupin Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Inc., has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in New Jersey. On information and belief, Lupin Ltd., itself and through its wholly owned subsidiary Lupin Inc., manufactures, markets, and/or sells generic drugs throughout the United States and within the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Lupin Ltd. is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Lupin Inc. and therefore the activities of Lupin Inc. in this jurisdiction are attributed to Lupin Ltd.

10. On information and belief, this Court has personal jurisdiction over Lupin Inc. because Lupin Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in New Jersey. On information and belief, Lupin Inc. manufactures, markets, and/or sells generic drugs throughout the United States and within the State of New Jersey and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

11. On information and belief, Lupin Inc. is registered to do business in New Jersey (business identification number 0100953673) and has appointed National Registered Agents, Inc., located at 100 Canal Pointe Blvd., Suite 212, Princeton, NJ 08540, as its registered agent for the receipt of service of process.

12. On information and belief, Lupin Ltd. and Lupin Inc. have availed themselves of the jurisdiction of this Court by initiating litigation in this Judicial District. *See, e.g.*, *Lupin Ltd. and Lupin Pharm. Inc. v. Merck, Sharp & Dohme Corp*., Civ. Action No. 10-683 (JAP)(TJB) (D.N.J.).

13. On information and belief, both Lupin Ltd. and Lupin Inc. have previously been sued in this District and have not challenged personal jurisdiction. *See, e.g.*, *AstraZeneca AB, et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 09-5405 (JAP)(TJB) (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 09-1007 (GEB)(MCA) (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.,* Civ. Action No. 10-1578 (DMC)(JAD) (D.N.J.); *Tibotec Inc. and Tibotec Pharm. v. Lupin Ltd., et al.,* Civ. Action No. 10-5957 (WHW)(MAS) (D.N.J.); *Novartis Corp., et al. v. Lupin Ltd. and Lupin Pharm. Inc.,* Civ. Action No. 06-5954 (GEB)(ES) (D.N.J.); and *Elan*

Int'l. Ltd. and Fournier Laboratories Ireland Ltd. v. Lupin Ltd. and Lupin Pharm. Inc, Civ. Action No. 09-1008 (GEB)(MCA) (D.N.J.).

14. On information and belief, the acts of Lupin Inc. complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Lupin Ltd.

15. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with New Jersey, including, but not limited to, the above-described contacts and the actions on behalf of Defendants in connection with ANDA No. 207415, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

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

The Patents-In-Suit

17. 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.

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. On June 9, 2015, the USPTO duly and lawfully issued the '302 patent, entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters." A copy of the '302 patent is attached hereto as Exhibit R.

The XYREM® Drug Product

35. 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.

36. 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, '062, and '302 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM®.

37. 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

38. Pursuant to Section 505 of the FFDCA, Lupin filed ANDA No. 207415 ("Lupin's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 500 mg/mL sodium oxybate oral solution ("Lupin's Proposed Product"), before the patents-in-suit expire.

39. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Lupin 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) ("Lupin's Paragraph IV Certification"), alleging that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, '306, '619, '062 and '302 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Lupin's ANDA.

40. No earlier than July 23, 2015, Jazz Pharmaceuticals received written notice of Lupin's Paragraph IV Certification ("Lupin's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Lupin's Notice Letter alleged that the claims of the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, '306, '619, '062, and '302 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Lupin's ANDA. Lupin's Notice Letter also informed Jazz Pharmaceuticals that Lupin seeks approval to market Lupin's Proposed Product before the patents-in-suit expire.

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

42. Under applicable laws and regulations, the FDA will not approve Lupin'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

43. Plaintiffs repeat and reallege the allegations of paragraphs 1-42 as though fully set forth herein.

44. Lupin, 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 use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the

expiration of the '431 patent. Lupin'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.

45. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

49. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe the '431 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's Proposed Product is

especially adapted for a use that infringes the '431 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

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

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

52. 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

53. Plaintiffs repeat and reallege the allegations of paragraphs 1-52 as though fully set forth herein.

54. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

direct infringement with knowledge of the '889 patent and knowledge that its acts are encouraging infringement.

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

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

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

61. 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

62. Plaintiffs repeat and reallege the allegations of paragraphs 1-61 as though fully set forth herein.

63. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

67. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe the '219 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes the '219 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

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

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

70. 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

71. Plaintiffs repeat and reallege the allegations of paragraphs 1-70 as though fully set forth herein.

72. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

75. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of the '506 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '506 patent and knowledge that its acts are encouraging infringement.

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

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

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

79. 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

80. Plaintiffs repeat and reallege the allegations of paragraphs 1-79 as though fully set forth herein.

81. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

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

and belief, Lupin has had and continues to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes the '650 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

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

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

88. 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

89. Plaintiffs repeat and reallege the allegations of paragraphs 1-88 as though fully set forth herein.

90. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

direct infringement with knowledge of the '275 patent and knowledge that its acts are encouraging infringement.

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

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

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

97. 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

98. Plaintiffs repeat and reallege the allegations of paragraphs 1-97 as though fully set forth herein.

99. Lupin, 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 use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '203 patent. Lupin'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.

100. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

103. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of the '203 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '203 patent and knowledge that its acts are encouraging infringement.

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

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

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

107. 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

108. Plaintiffs repeat and reallege the allegations of paragraphs 1-107 as though fully set forth herein.

109. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

113. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe the '730 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's Proposed Product is

especially adapted for a use that infringes the '730 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

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

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

116. 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

117. Plaintiffs repeat and reallege the allegations of paragraphs 1-116 as though fully set forth herein.

118. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

direct infringement with knowledge of the '106 patent and knowledge that its acts are encouraging infringement.

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

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

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

125. 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

126. Plaintiffs repeat and reallege the allegations of paragraphs 1-125 as though fully set forth herein.

127. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

131. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe the '107 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes the '107 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

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

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

134. 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

135. Plaintiffs repeat and reallege the allegations of paragraphs 1-134 as though fully set forth herein.

136. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

139. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of the '059 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '059 patent and knowledge that its acts are encouraging infringement.

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

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

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

143. 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

144. Plaintiffs repeat and reallege the allegations of paragraphs 1-143 as though fully set forth herein.

145. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

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

and belief, Lupin has had and continues to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes the '988 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

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

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

152. 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

153. Plaintiffs repeat and reallege the allegations of paragraphs 1-152 as though fully set forth herein.

154. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

direct infringement with knowledge of the '182 patent and knowledge that its acts are encouraging infringement.

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

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

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

161. 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

162. Plaintiffs repeat and reallege the allegations of paragraphs 1-161 as though fully set forth herein.

163. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

167. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe the '963 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes the '963 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

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

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

170. 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

171. Plaintiffs repeat and reallege the allegations of paragraphs 1-170 as though fully set forth herein.

172. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

175. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of the '306 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '306 patent and knowledge that its acts are encouraging infringement.

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

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

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

179. 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

180. Plaintiffs repeat and reallege the allegations of paragraphs 1-179 as though fully set forth herein.

181. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

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

and belief, Lupin has had and continues to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes the '619 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

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

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

188. 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

189. Plaintiffs repeat and reallege the allegations of paragraphs 1-188 as though fully set forth herein.

190. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, 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).

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

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

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

direct infringement with knowledge of the '062 patent and knowledge that its acts are encouraging infringement.

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

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

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

197. 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 XVIII: Infringement of the '302 Patent

198. Plaintiffs repeat and reallege the allegations of paragraphs 1-197 as though fully set forth herein.

199. Lupin's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of sodium oxybate oral solution, prior to the expiration of the '302 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

200. There is a justiciable controversy between the parties hereto as to the infringement of the '302 patent.

201. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe the '302 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States.

202. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of the '302 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '302 patent and knowledge that its acts are encouraging infringement.

203. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe the '302 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Lupin's Proposed Product in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes the '302 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

204. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin's infringement of the '302 patent is not enjoined.

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

206. 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 Lupin has infringed the patents-in-suit by submitting ANDA No. 207415;

(B) A Judgment be entered that Lupin has infringed, and that Lupin's making, using, selling, offering to sell, or importing Lupin'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. 207415 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 Lupin 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 Lupin'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 Lupin, 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 Lupin's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Lupin 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 Lupin engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Lupin'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: September 1, 2015

By: s/ Charles M. Lizza

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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), *Jazz Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*, Civil Action No. 15-4532 (ES)(JAD), and *Jazz Pharmaceuticals, Inc. v. Wockhardt Bio AG, et al.*, Civil Action No. 15-5619 (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: September 1, 2015

By: s/ Charles M. Lizza

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