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**

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| **JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**ROXANE LABORATORIES, INC.,**<br><br>**Defendant.** | **Civil Action No. _____**<br><br>**COMPLAINT FOR PATENT INFRINGEMENT**<br><br>**(Filed Electronically)** |

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz Pharmaceuticals"), by their undersigned attorneys, for their Complaint against defendant Roxane Laboratories, Inc. ("Roxane"), 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 Roxane'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. 8,461,203 (the "'203 patent"),

8,772,306 (the "'306 patent"), and 8,859,619 (the "'619 patent") owned by Jazz Pharmaceuticals (collectively, "the patents-in-suit").

**The Parties**

2. Plaintiff Jazz Pharmaceuticals 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 4, Ireland.

4. Defendant Roxane is a corporation organized under the laws of Nevada, having a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

5. On information and belief, Roxane is registered to do business in the State of New Jersey, and maintains a registered agent for service of process in New Jersey. On information and belief, Roxane regularly transacts business within this Judicial District. Further, on information and belief, Roxane develops numerous generic drugs for sale and use throughout the United States, including in this Judicial District. Roxane has litigated patent cases in this District in the past without contesting personal jurisdiction, and, in at least some of those actions, Roxane has asserted counterclaims.

**Jurisdiction and Venue**

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

7. This Court has personal jurisdiction over Roxane by virtue of, *inter alia,* its systematic and continuous contacts with the State of New Jersey. On information and belief, Roxane has purposefully availed itself of this forum by, among other things, making, shipping,

using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Further, on information and belief, Roxane has customers in the State of New Jersey.

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

**The Patents-In-Suit**

9. 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 A.

10. 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 B.

11. On October 14, 2014, the 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 C.

**The XYREM® Drug Product**

12. 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.

13. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '306 and '619 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to XYREM®.

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

**Acts Giving Rise to This Suit**

15. Pursuant to Section 505 of the FFDCA, Roxane filed ANDA No. 202-090 ("Roxane'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 ("Roxane's Proposed Product"), before the patents-in-suit expire.

16. In connection with the filing of its ANDA as described in the preceding paragraph, Roxane has provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Roxane's Paragraph IV Certifications"), alleging that the claims of the '306 and '619 patents and other Orange-Book-listed patents owned by Jazz Pharmaceuticals are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA.

17. No earlier than January 15, 2015, Jazz Pharmaceuticals received written notice of Roxane's Paragraph IV Certification ("Roxane's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B) with respect to the '306 and '619 patents. Roxane's Notice Letter alleged that the claims of the '306 and '619 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Roxane's ANDA. Roxane's Notice Letter also informed Jazz Pharmaceuticals that Roxane seeks approval to market Roxane's Proposed Product before the '306 and '619 patents expire.

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

19. Under applicable laws and regulations, the FDA will not approve Roxane'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 '203 Patent**

20. Plaintiffs repeat and reallege the allegations of paragraphs 1-19 as though fully set forth herein.

21. Roxane, through its submission of its Paragraph IV Certifications 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. Roxane'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.

22. Roxane'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).

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

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

25. Unless enjoined by this Court, upon FDA approval of Roxane's ANDA, Roxane will induce infringement of the '203 patent under 35 U.S.C. § 271(b) by making, using, offering

to sell, importing, and/or selling Roxane's Proposed Product in the United States. On information and belief, upon FDA approval of Roxane's ANDA, Roxane will intentionally encourage acts of direct infringement with knowledge of the '203 patent and knowledge that its acts are encouraging infringement.

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

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

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

29. 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 '306 Patent**

30. Plaintiffs repeat and reallege the allegations of paragraphs 1-29 as though fully set forth herein.

31. Roxane'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).

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

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

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

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

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

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

38. 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 '619 Patent**

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

40. Roxane'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).

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

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

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

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

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

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

47. 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 Roxane has infringed the patents-in-suit by submitting ANDA No. 202-090;

(B) A Judgment be entered that Roxane has infringed, and that Roxane's making, using, selling, offering to sell, or importing Roxane'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. 202-090 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 Roxane 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 Roxane'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 Roxane, 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 Roxane's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Roxane has committed any acts with respect to the 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 Roxane engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Roxane'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: February 20, 2015

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com
wbaton@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. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 14-3235 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Ranbaxy Laboratories Ltd., et al.*, Civil Action No. 14-4467 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, Civil Action No. 14-5139 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Par Pharmaceutical, Inc.*, Civil Action No. 14-6150 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Ranbaxy Laboratories Ltd., et al.*, Civil Action No. 14- 6151 (ES)(JAD), *Jazz Pharmaceuticals, Inc., et al. v. Watson Laboratories, Inc.*, Civil Action No. 14-7757 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, Civil Action No. 15-173 (ES)(JAD), *Jazz Pharmaceuticals, Inc. v. Ranbaxy Laboratories Ltd., et al.*, Civil Action No. 15-187 (ES)(JAD), and *Jazz Pharmaceuticals, Inc., et al. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 15-1043 (ES)(JAD), are related to the matter in controversy because they involve 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: February 20, 2015

By: s/ Charles M. Lizza

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

*Attorneys for Plaintiffs*
*Jazz Pharmaceuticals, Inc. and*
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*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