UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. LUPIN LTD., LUPIN PHARMACEUTICALS, INC., and LUPIN INC. Defendants.	Consolidated Action No. 13-391(ES)(JAD) **FILED ELECTRONICALLY** **JURY TRIAL DEMANDED**

LUPIN LIMITED'S, LUPIN PHARMACEUTICALS, INC.'S AND LUPIN INC.'S ANSWER, DEFENSES AND COUNTERCLAIMS TO FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendants Lupin Limited, Lupin Pharmaceuticals, Inc. ("LPI") and Lupin Inc. (collectively, "Lupin") hereby answer the First Amended Complaint for Patent Infringement of Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Plaintiffs" or "Jazz"), for which every allegation not expressly admitted is denied, 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"). Pursuant to Fed. R. Civ. P. 15(c), the claims of infringement of the patents-in-suit against Lupin Inc. relate back to the September 1, 2015 filing date of the original complaint.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that this is an action for alleged patent infringement and that Lupin Inc. submitted an Abbreviated New Drug Application ("ANDA") seeking approval of the U.S. Food and Drug Administration ("FDA") for Sodium Oxybate Oral Solution, 500 mg/ml. Further answering, Lupin denies that Lupin Limited and LPI are proper parties to this action. Lupin denies all remaining allegations of Paragraph 1.

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.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies the same.

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.

ANSWER: Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies the same.

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 District, either on its own or through its affiliates, including LPI. and Lupin Inc.

ANSWER: Lupin admits that Lupin Limited is an Indian corporation, organized and existing solely under the laws of India, with its only place of business in India, including at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India. Lupin further admits that Lupin Limited develops and manufactures pharmaceutical products, including quality generic medicines. Lupin denies that Lupin Limited is a proper party to this action. Lupin denies all remaining allegations of Paragraph 4.

5. Lupin Ltd.'s 2015 Annual Report identifies LPI and Lupin Inc. as subsidiaries of Lupin Ltd.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Limited's 2015 Annual Report, *available at* http://www.lupin.com/annual-report.php ("2015 Annual Report"), states that "Lupin Inc., USA (LINC) [is a] wholly owned subsidiary of [Lupin Atlantic Holdings SA]." Lupin also admits that Lupin's 2015 Annual Report states that "[t]he entire shareholdings of Lupin Inc. . . . are held by Lupin Atlantic Holdings SA, Switzerland, the wholly-owned subsidiary of the Company." Lupin further admits that Lupin's 2015 Annual Report states that "shares of Lupin Pharmaceuticals Inc., U.S.A. are held by Lupin Inc., U.S.A. (97%) and Lupin

Limited (3%)." Further answering, Lupin denies that Lupin Limited and LPI are proper parties to this action. Lupin denies all remaining allegations of Paragraph 5.

6. On information and belief, Defendant LPI 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, LPI 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, including Lupin Ltd. and Lupin Inc.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that LPI is a Virginia corporation having a place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin further admits that LPI distributes and sells generic drug products. Further answering, Lupin denies that LPI is a proper party to this action. Lupin denies all remaining allegations of Paragraph 6.

7. On information and belief, LPI is a wholly owned subsidiary and agent of Lupin Ltd. On information and belief, LPI is a subsidiary and agent of Lupin Inc. On information and belief, LPI acts at the direction of, under the control of, and for the direct benefit of Lupin Ltd. and Lupin Inc. and is controlled and/or dominated by Lupin Ltd and Lupin Inc. On information and belief, LPI, Lupin Ltd., and Lupin Inc. have at least one officer or director in common. Lupin Ltd.'s 2015 Annual Report states that "[t]he shares of [LPI] are held by Lupin lnc.[] (97%) and Lupin Limited (3%). . . . The entire shareholdings in Lupin Inc. . . . are held by Lupin Atlantis[], the wholly owned subsidiary of [Lupin Ltd.]."

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the 2015 Annual Report, specifically Annexure "A" to the Directors' Report, Form AOC – 1 states that "shares of Lupin Pharmaceuticals Inc., U.S.A. are held by Lupin Inc., U.S.A. (97 %) and Lupin Limited (3 %)." Lupin further admits that the 2015 Annual Report states "[t]he entire shareholdings in Lupin Inc., U.S.A., Lupin GmbH, Switzerland, Nanomi B.V., Netherlands and Laboratorios Grin S.A. de C.V., Mexico are held by Lupin Atlantis Holdings SA, Switzerland, the wholly-owned subsidiary of the Company." Further answering, Lupin denies that Lupin Limited and LPI are proper parties to this action. Lupin denies all remaining allegations of Paragraph 7.

8. On information and belief, LPI is Lupin Ltd.'s and Lupin Inc.'s marketing and sales agent in the United States, engaged in the sale and distribution of generic pharmaceutical products throughout the United States, including in the state of New Jersey.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

9. On information and belief, Lupin Inc. is a corporation organized and existing under the laws of the state of Maryland, having its 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 and/or agents, including Lupin Ltd. and LPI.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Inc. is a Maryland corporation having a place of business at 111 South Calvert Street, Baltimore, Maryland 21202. Lupin denies all remaining allegations of Paragraph 9.

10. On information and belief, Lupin Inc. is a wholly owned subsidiary and agent of Lupin Ltd. On information and belief, Lupin Inc. acts at the direction of, under the control of, and for the direct benefit of Lupin Ltd. and is controlled and/or dominated by Lupin Ltd. On information and belief, Lupin Inc. and Lupin Ltd. have at least one officer or director in common. Lupin Ltd.'s 2015 Annual Report states that "[t]he entire shareholdings in Lupin Inc. . . . are held by Lupin Atlantis[], the wholly owned subsidiary of [Lupin Ltd.]."

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the 2015 Annual Report, specifically Annexure A to the Director's Report, Form No. AOC-1, states "[t]he entire shareholdings in Lupin Inc., U.S.A., Lupin GmbH, Switzerland, Nanomi B.V., Netherlands and Laboratorios Grin S.A. de C.V., Mexico are held by Lupin Atlantis Holdings SA, Switzerland, the wholly-owned subsidiary of the Company." Further answering, Lupin denies that Lupin Limited is a proper party to this action. Lupin denies all remaining allegations of Paragraph 10.

11. On information and belief, Lupin Inc. and LPI have the same business address, business email address, and business phone number. On information and belief, employees of Lupin Inc. are also employees of LPI, or at a minimum, hold themselves out to be employees of LPI.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Inc. has an address at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin further admits that LPI has an address at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Further answering, Lupin denies that LPI is a proper party to this action. Lupin denies all remaining allegations of Paragraph 11.

12. On information and belief, Defendants hold themselves out as a single entity for the purposes of the manufacture, sale, marketing, distribution, and importation of generic drug products.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

13. On information and belief, following any FDA approval of ANDA No. 207415, Defendants Lupin Ltd., LPI, 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.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

Jurisdiction and Venue

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

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

15. 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 subsidiaries LPI and 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 subsidiaries Lupin Inc. and LPI, 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 LPI, and therefore the activities of Lupin Inc. and LPI in this jurisdiction are attributed to Lupin Ltd.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited is a proper party to this action.

16. On information and belief, this Court has personal jurisdiction over LPI. because LPI 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, LPI 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.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that LPI is a proper party to this action.

17. On information and belief, LPI 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.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that LPI has registered to

do business in New Jersey. Further answering, Lupin denies that LPI is a proper party to this action. Lupin denies the remaining allegations of Paragraph 17.

18. On information and belief, Lupin Inc. is subject to personal jurisdiction in New Jersey because, among other things, Lupin Inc., itself and through its subsidiary LPI, 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., itself and through its subsidiary LPI, 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 Inc. is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates LPI, and therefore the activities of LPI in this jurisdiction are attributed to Lupin Inc.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

19. On information and belief, Lupin Ltd. and LPI have availed themselves of the jurisdiction of this court by initiating litigation in this District. *See, e.g., Lupin Ltd. and Lupin Pharm. Inc. v. Merck, Sharp & Dohme Corp.*, Civ. Action No. 3:10-CV-683 (JAP)(TJB) (D.N.J.).

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

20. On information and belief, both Lupin Ltd. and LPI 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. 3:09-cv-05404 (JAP)(TJB) (D.N.J.); *Abbott Labs and Laboratoires Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:09-cv-01007 (GEB)(MCA) (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:10-cv-01578 (DMC)(JAD) (D.N.J.); *Tibotec Inc. and Tibotec Pharm. v. Lupin Ltd., et al.*, Civ. Action No. 2:10-cv-05954 (WHW)(MAS) (D.N.J.); *Novartis Corp., et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:06-cv-05954-(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. 2:09-cv-01008 (GEB)(MCA) (D.N.J.).

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

21. On information and belief, the acts of LPI and 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.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

22. 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.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

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

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

The Patents-In-Suit

24. 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.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the United States Patent and Trademark Office ("PTO"), on or about October 29, 2002, the PTO issued United States Patent No. 6,472,431 B2 ("the '431 patent"), entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy,"

and that what purports to be a copy of the ‘431 patent is attached to the Complaint as Exhibit A. Lupin denies that the ‘431 patent was lawfully issued, and any suggestion or implication the ‘431 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 24.

25. 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.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about August 24, 2004, the PTO issued United States Patent No. 6,780,889 B2 (“the ‘889 patent”), entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy,” and that what purports to be a copy of the ‘889 patent is attached to the Complaint as Exhibit B. Lupin denies that the ‘889 patent was lawfully issued, and any suggestion or implication the ‘889 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 25.

26. 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.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about August 28, 2007, the PTO issued United States Patent No. 7,262,219 B2 (“the ‘219 patent”), entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy,” and that what purports to be a copy of the ‘219 patent is attached to the Complaint as Exhibit C. Lupin denies that the ‘219 patent was lawfully issued, and any suggestion or implication the ‘219 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 26.

27. 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.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about December 14 , 2010, the PTO issued United States Patent No. 7,851,506 B2 (“the ‘506 patent”), entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy,” and that what purports to be a copy of the ‘506 patent is attached to the Complaint as Exhibit D. Lupin denies that the ‘506 patent was lawfully issued, and any suggestion or implication the ‘506 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 27.

28. 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.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about September 11, 2012, the PTO issued United States Patent No. 8,263,650 B2 (“the ‘650 patent”), entitled “Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy,” and that what purports to be a copy of the ‘650 patent is attached to the Complaint as Exhibit E. Lupin denies that the ‘650 patent was lawfully issued, and any suggestion or implication the ‘650 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 28.

29. 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.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the

PTO, on or about December 4, 2012, the PTO issued United States Patent No. 8,324,275 B2 ("the '275 patent"), entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," and that what purports to be a copy of the '275 patent is attached to the Complaint as Exhibit F. Lupin denies that the '275 patent was lawfully issued, and any suggestion or implication the '275 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 29.

30. 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.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about June 11, 2013, the PTO issued United States Patent No. 8,461,203 B2 ("the '203 patent"), entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," and that what purports to be a copy of the '203 patent is attached to the Complaint as Exhibit G. Lupin denies that the '203 patent was lawfully issued, and any suggestion or implication the '203 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 30.

31. 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.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about February 23, 2010, the PTO issued United States Patent No. 7,668,730 B2 ("the '730 patent"), entitled "Sensitive Drug Distribution System and Method," and that what purports to be a copy of the '730 patent is attached to the Complaint as Exhibit H. Lupin denies that the '730 patent was lawfully issued, and any suggestion or implication the '730 patent is

valid or enforceable. Lupin denies the remaining allegations of Paragraph 31.

32. 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.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about July 27, 2010, the PTO issued United States Patent No. 7,765,106 B2 (“the ‘106 patent”), entitled “Sensitive Drug Distribution System and Method,” and that what purports to be a copy of the ‘106 patent is attached to the Complaint as Exhibit I. Lupin denies that the ‘106 patent was lawfully issued, and any suggestion or implication the ‘106 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 32.

33. 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.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about July 27, 2010, the PTO issued United States Patent No. 7,765,107 B2 (“the ‘107 patent”), entitled “Sensitive Drug Distribution System and Method,” and that what purports to be a copy of the ‘107 patent is attached to the Complaint as Exhibit J. Lupin denies that the ‘107 patent was lawfully issued, and any suggestion or implication the ‘107 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 33.

34. 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.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about February 22, 2011, the PTO issued United States Patent No. 7,895,059 B2

("the '059 patent"), entitled "Sensitive Drug Distribution System and Method," and that what purports to be a copy of the '059 patent is attached to the Complaint as Exhibit K. Lupin denies that the '059 patent was lawfully issued, and any suggestion or implication the '059 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 34.

35. 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.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about June 4, 2013, the PTO issued United States Patent No. 8,457,988 B1 ("the '988 patent"), entitled "Sensitive Drug Distribution System and Method," and that what purports to be a copy of the '988 patent is attached to the Complaint as Exhibit L. Lupin denies that the '988 patent was lawfully issued, and any suggestion or implication the '988 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 35.

36. 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.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about November 19, 2013, the PTO issued United States Patent No. 8,589,182 B1 ("the '182 patent"), entitled "Sensitive Drug Distribution System and Method," and that what purports to be a copy of the '182 patent is attached to the Complaint as Exhibit M. Lupin denies that the '182 patent was lawfully issued, and any suggestion or implication the '182 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 36.

37. 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.

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about May 20, 2014, the PTO issued United States Patent No. 8,731,963 B1 ("the '963 patent"), entitled "Sensitive Drug Distribution System and Method," and that what purports to be a copy of the '963 patent is attached to the Complaint as Exhibit N. Lupin denies that the '963 patent was lawfully issued, and any suggestion or implication the '963 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 37.

38. 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.

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about July 8, 2014, the PTO issued United States Patent No. 8,772,306 B1 ("the '306 patent"), entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters," and that what purports to be a copy of the '306 patent is attached to the Complaint as Exhibit O. Lupin denies that the '306 patent was lawfully issued, and any suggestion or implication the '306 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 38.

39. 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.

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about October 14, 2014, the PTO issued United States Patent No. 8,859,619 B2 ("the '619 patent"), entitled "Microbiologically Sound and Stable Solutions of Gamma-

Hydroxybutyrate Salt for the Treatment of Narcolepsy," and that what purports to be a copy of the '619 patent is attached to the Complaint as Exhibit P. Lupin denies that the '619 patent was lawfully issued, and any suggestion or implication the '619 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 39.

40. 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.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about February 10, 2015, the PTO issued United States Patent No. 8,952,062 B2 ("the '062 patent"), entitled "Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy," and that what purports to be a copy of the '062 patent is attached to the Complaint as Exhibit Q. Lupin denies that the '062 patent was lawfully issued, and any suggestion or implication the '062 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 40.

41. 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.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, according to the electronic records of the PTO, on or about June 9, 2015, the PTO issued United States Patent No. 9,050,302 B2 ("the '302 patent"), entitled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters," and that what purports to be a copy of the '302 patent is attached to the Complaint as Exhibit R. Lupin denies that the '302 patent was lawfully issued, and any suggestion or implication the '302 patent is valid or enforceable. Lupin denies the remaining allegations of Paragraph 41.

The XYREM® Drug Product

42. 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.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "Jazz Pharmaceuticals" as the purported "Applicant" for New Drug Application ("NDA") No. 21-196 for XYREM®. Lupin denies the remaining allegations of Paragraph 42.

43. 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®.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the Orange Book identifies the '889, '219, '506, '650, '275, '730, '106, '107, '059, '988, '182, '963, '306, '619, '062, and '302 patents in the "Patent Data" under the listing for XYREM®. Lupin denies the remaining allegations of Paragraph 43.

44. 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.

ANSWER: Paragraph 44 contains legal conclusion to which no answer is required. To the extent an answer is required, denied.

Acts Giving Rise to This Suit

45. Pursuant to Section 505 of the FFDCA, Lupin filed ANDA No. 207415 ("Lupin'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 ("Lupin's Proposed Product"), before the patents-in-suit expire.

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Inc. submitted an ANDA seeking approval of FDA for Sodium Oxybate Oral Solution, 500 mg/ml. Further answering, Lupin denies that Lupin Limited and LPI are proper parties to this action. Lupin denies the remaining allegations of Paragraph 45.

46. 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.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, in a letter dated July 21, 2015, Lupin Inc. gave written notification to, among others, Plaintiffs that Lupin Inc. filed an ANDA with FDA seeking approval for Sodium Oxybate Oral Solution, 500 mg/ml, which ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) stating, among other things, that in Lupin Inc.'s opinion and to the best of its knowledge, 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. Lupin denies the remaining allegations of Paragraph 46.

47. 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.

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that, in a letter dated July 21, 2015, Lupin Inc.

gave written notification to, among others, Plaintiffs that Lupin Inc. filed an ANDA with FDA seeking approval for Sodium Oxybate Oral Solution, 500 mg/ml, which ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) stating, among other things, that in Lupin Inc.'s opinion and to the best of its knowledge, 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. Lupin denies the remaining allegations of Paragraph 47.

48. 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.

ANSWER: Paragraph 48 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that Lupin Inc.'s ANDA does not currently contain a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii). Lupin denies all remaining allegations of Paragraph 48.

49. 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.

ANSWER: Paragraph 49 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Lupin further denies that Lupin Limited and LPI are proper parties to this action.

Count I: the '431 Patent

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

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-49 as if fully set forth herein.

51. 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 manufacture, use, 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.

ANSWER: Denied.

52. Lupin’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).

ANSWER: Denied.

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

ANSWER: Denied.

54. 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, selling, offering to sell, and/or importing Lupin’s Proposed Product in the United States.

ANSWER: Denied.

55. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

56. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin’s Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

59. 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.

ANSWER: Denied.

Count II: the '889 Patent

60. Plaintiffs repeat and reallege the allegations of paragraphs 1-59 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-59 as if fully set forth herein.

61. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

63. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

64. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

65. 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, selling,

offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

68. 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.

ANSWER: Denied.

Count III: the '219 Patent

69. Plaintiffs repeat and reallege the allegations of paragraphs 1-68 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-68 as if fully set forth herein.

70. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

72. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

73. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

74. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

77. 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.

ANSWER: Denied.

Count IV: the '506 Patent

78. Plaintiffs repeat and reallege the allegations of paragraphs 1-77 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-77 as if fully set forth herein.

79. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

81. 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, selling, offering to sell, and/or importing Lupin’s Proposed Product in the United States.

ANSWER: Denied.

82. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

83. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin’s Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

86. 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.

ANSWER: Denied.

Count V: the ’650 Patent

87. Plaintiffs repeat and reallege the allegations of paragraphs 1-86 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-86 as if fully set forth herein.

88. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

90. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

91. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

92. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

95. 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.

ANSWER: Denied.

Count VI: the '275 Patent

96. Plaintiffs repeat and reallege the allegations of paragraphs 1-95 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-95 as if fully set forth herein.

97. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

99. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

100. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

101. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin’s Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

104. 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.

ANSWER: Denied.

Count VII: the ’203 Patent

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

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-104 as if fully set forth herein.

106. 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 manufacture, use, 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.

ANSWER: Denied.

107. Lupin’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).

ANSWER: Denied.

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

ANSWER: Denied.

109. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

110. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

111. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

114. 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.

ANSWER: Denied.

Count VIII: the '730 Patent

115. Plaintiffs repeat and reallege the allegations of paragraphs 1-114 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-114 as if fully set forth herein.

116. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

118. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

119. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

120. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

123. 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.

ANSWER: Denied.

Count IX: the '106 Patent

124. Plaintiffs repeat and reallege the allegations of paragraphs 1-123 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-123 as if fully set forth herein.

125. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

127. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

128. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

129. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin’s Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

132. 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.

ANSWER: Denied.

Count X: the ’107 Patent

133. Plaintiffs repeat and reallege the allegations of paragraphs 1-132 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-132 as if fully set forth herein.

134. Lupin’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).

ANSWER: Denied.

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

ANSWER: Denied.

136. 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, selling, offering to sell, and/or importing Lupin’s Proposed Product in the United States.

ANSWER: Denied.

137. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

138. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

141. 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.

ANSWER: Denied.

Count XI: the '059 Patent

142. Plaintiffs repeat and reallege the allegations of paragraphs 1-141 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-141 as if fully set forth herein.

143. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

145. 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, selling, offering to sell, and/or importing Lupin’s Proposed Product in the United States.

ANSWER: Denied.

146. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

147. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin’s Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

150. 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.

ANSWER: Denied.

Count XII: the ’988 Patent

151. Plaintiffs repeat and reallege the allegations of paragraphs 1-150 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-150 as if fully set forth herein.

152. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

154. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

155. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

156. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

159. 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.

ANSWER: Denied.

Count XIII: the '182 Patent

160. Plaintiffs repeat and reallege the allegations of paragraphs 1-159 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-159 as if fully set forth herein.

161. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

163. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

164. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

165. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin’s Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

168. 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.

ANSWER: Denied.

Count XIV: the ’963 Patent

169. Plaintiffs repeat and reallege the allegations of paragraphs 1-168 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-168 as if fully set forth herein.

170. Lupin’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).

ANSWER: Denied.

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

ANSWER: Denied.

172. 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, selling, offering to sell, and/or importing Lupin’s Proposed Product in the United States.

ANSWER: Denied.

173. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

174. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

177. 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.

ANSWER: Denied.

Count XV: the '306 Patent

178. Plaintiffs repeat and reallege the allegations of paragraphs 1-177 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-177 as if fully set forth herein.

179. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

181. 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, selling, offering to sell, and/or importing Lupin’s Proposed Product in the United States.

ANSWER: Denied.

182. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

183. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin’s Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

186. 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.

ANSWER: Denied.

Count XVI: the ’619 Patent

187. Plaintiffs repeat and reallege the allegations of paragraphs 1-186 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-186 as if fully set forth herein.

188. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

190. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

191. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

192. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

195. 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.

ANSWER: Denied.

Count XVII: the '062 Patent

196. Plaintiffs repeat and reallege the allegations of paragraphs 1-195 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-195 as if fully set forth herein.

197. Lupin'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).

ANSWER: Denied.

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

ANSWER: Denied.

199. 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, selling, offering to sell, and/or importing Lupin's Proposed Product in the United States.

ANSWER: Denied.

200. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

201. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin’s Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

204. 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.

ANSWER: Denied.

Count XVIII: the ’302 Patent

205. Plaintiffs repeat and reallege the allegations of paragraphs 1-204 as though fully set forth herein.

ANSWER: Lupin restates, reasserts and incorporates by reference herein its responses to Paragraphs 1-204 as if fully set forth herein.

206. Lupin’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 ’302 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

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

ANSWER: Denied.

208. 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, selling, offering to sell, and/or importing Lupin’s Proposed Product in the United States.

ANSWER: Denied.

209. 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, selling, offering to sell, and/or importing 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.

ANSWER: Denied.

210. 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, selling, offering to sell, and/or importing 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 noninfringing use for Lupin's Proposed Product.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

213. 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.

ANSWER: Denied.

* * *

Lupin denies all allegations not expressly admitted herein. Lupin further denies that Jazz is entitled to any of the relief requested, or to any relief whatsoever, and requests that this action be dismissed with prejudice, and that Lupin be awarded its fees and costs in defending this action, together with any further relief the Court deems just and proper.

SEPARATE DEFENSES

Without prejudice to the denials set forth in their Answer, without admitting any averments of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Lupin Limited, Lupin Pharmaceuticals, Inc. ("LPI") and Lupin Inc. (collectively, "Lupin") aver and assert the following separate defenses to the Complaint:

First Defense

The claims of the '431, '889, '219, '506, '650, '275, '203, '730, '106, '107, '059, '988, '182, '963, '306, '619, '062 and '302 patents (collectively, the "Patents-in-Suit") are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code. Among other things, the claims lack utility and/or encompass inoperable subject matter in violation of 35 U.S.C. § 101; fail to differentiate over existing prior art, uses and knowledge in violation of 35 U.S.C. § 102; fail to constitute non-obvious subject matter in violation of 35 U.S.C. § 103; are indefinite, non-enabled, and/or lack written description support in violation of 35 U.S.C. § 112; violate dependent claiming requirements of 35 U.S.C. § 112; violate the prohibition against double-patenting; upon information and belief fail to state the correct inventive entity in violation of 35 U.S.C. § 102(f); and/or encompass alleged inventions abandoned and/or forfeited. *See* 35 U.S.C. § 102(c).

Second Defense

The manufacture, sale, use, offer for sale, and/or importation of the proposed Sodium Oxybate Oral Solution 500 mg/mL that is the subject of Abbreviated New Drug Application ("ANDA") No. 207415 would not infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents.

Third Defense

Lupin has not induced, does not induce, and will not induce, infringement of any valid and/or enforceable claim of the Patents-in-Suit.

Fourth Defense

Lupin has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the Patents-in-Suit.

Fifth Defense

Plaintiffs' are precluded from asserting the Patents-in-Suit against Lupin under the doctrine of collateral estoppel.

Sixth Defense

LPI is not a proper party to this action.

Seventh Defense

Lupin Limited is not a proper party to this action.

Eighth Defense

The Complaint fails to state a claim upon which relief can be granted.

Ninth Defense

The Court lacks subject matter jurisdiction for any claims asserted against LPI and Lupin Limited.

Tenth Defense

The Complaint fails to state a claim for willful infringement and/or exceptional case.

Eleventh Defense

The Complaint is not brought by any party that has standing to claim a remedy, nor does it allege facts sufficient to state a viable claim to any remedy requested by any Plaintiff.

Twelfth Defense

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

Thirteenth Defense

Any defense asserted in any related litigation, including but not limited to defenses asserted in *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.,* Civil Action No. 10-6108(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.,* Civil Action No. 15-1360(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.,* Civil Action No. 16-469(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 13-391(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 15-6562(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, Civil Action No. 15-7580(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. et al. v. Wockhardt Bio AG et al.*, Civil Action No. 16-0099(ES) (D.N.J.); and, *Jazz Pharmaceuticals, Inc. v. Sun Pharmaceuticals Industries Ltd.*, Civil Action No. 15-8229(ES) (D.N.J.).

COUNTERCLAIMS

To the extent the Court has subject matter jurisdiction for the claims asserted by Plaintiffs in this action, Defendants/Counterclaim-Plaintiffs, Lupin Limited, Lupin Pharmaceuticals, Inc. ("LPI") and Lupin Inc. (collectively, "Lupin"), assert the following Counterclaims against Plaintiffs/Counterclaim-Defendants Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz" or "Plaintiffs"), as follows:

Parties

1. Lupin Limited is an Indian corporation located solely in India, having a place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India.

2. Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

3. Lupin Inc. is a corporation organized and existing under the laws of the State of Maryland, having a place of business at 111 South Calvert Street, Baltimore, Maryland 21202.

4. Plaintiff/Counterclaim-Defendant Jazz Pharmaceuticals, Inc. purports to be 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.

5. Plaintiff/Counterclaim-Defendant Jazz Pharmaceuticals Ireland Limited purports to be 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.

Jurisdiction and Venue

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Lupin in this District, and/or because Plaintiffs conduct substantial business in this District.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Patents-in-Suit

10. On or about October 29, 2002, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,472,431 B2 ("the '431 patent") entitled *Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy*, to Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan.

11. On or about August 24, 2004, the PTO issued U.S. Patent No. 6,780,889 B2 ("the '889 patent") entitled *Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy*, to Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan.

12. On or about August 28, 2007, the PTO issued U.S. Patent No. 7,262,219 B2 ("the '219 patent") entitled *Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy*, to Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan.

13. On or about December 14, 2010, the PTO issued U.S. Patent No. 7,851,506 B2 ("the '506 patent") entitled *Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy*, to Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan.

14. On or about September 11, 2012, the PTO issued U.S. Patent No. 8,263,650 B2 ("the '650 patent") entitled *Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy,* to Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton T. Reardan.

15. On or about December 4, 2012, the PTO issued U.S. Patent No. 8,324,275 ("the '275 patent") entitled *Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy,* to Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton T. Reardan.

16. On or about June 11, 2013, the PTO issued U.S. Patent No. 8,461,203 B2 ("the '203 patent") entitled *Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy,* to Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton T. Reardan.

17. On or about February 23, 2010, the PTO issued U.S. Patent No. 7,668,730 B2 ("the '730 patent") entitled *Sensitive Drug Distribution System and Method,* to Dayton T. Reardan, Patti Engle and Bob Gagne.

18. On or about July 27, 2010, the PTO issued U.S. Patent No. 7,765,106 B2 ("the '106 patent") entitled *Sensitive Drug Distribution System and Method,* to Dayton T. Reardan, Patti A. Engel and Bob Gagne.

19. On or about July 27, 2010, the PTO issued U.S. Patent No. 7,765,107 B2 ("the '107 patent") entitled *Sensitive Drug Distribution System and Method,* to Dayton T. Reardan, Patti A. Engel and Bob Gagne.

20. On or about February 22, 2011, the PTO issued U.S. Patent No. 7,895,059 B2 ("the '059 patent") entitled *Sensitive Drug Distribution System and Method*, to Dayton T. Reardan, Patti A. Engel and Bob Gagne.

21. On or about June 4, 2013, the PTO issued U.S. Patent No. 8,457,988 B1 ("the '988 patent") entitled *Sensitive Drug Distribution System and Method*, to Dayton T. Reardan, Patti A. Engel and Bob Gagne.

22. On or about November 19, 2013, the PTO issued U.S. Patent No. 8,589,182 B1 ("the '182 patent") entitled *Sensitive Drug Distribution System and Method*, to Dayton T. Reardan, Patti A. Engel and Bob Gagne.

23. On or about May 20, 2014, the PTO issued U.S. Patent No. 8,731,963 B1 ("the '963 patent") entitled *Sensitive Drug Distribution System and Method*, to Dayton T. Reardan, Patti A. Engel and Bob Gagne.

24. On or about July 8, 2014, the PTO issued U.S. Patent No. 8,772,306 B1 ("the '306 patent") entitled *Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters*, to Mark Eller.

25. On or about October 14, 2014, the PTO issued U.S. Patent No. 8,859,619 B2 ("the '619 patent") entitled *Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy*, to Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton T. Reardan.

26. On or about February 10, 2015, the PTO issued U.S. Patent No. 8,952,062 B2 ("the '062 patent") entitled *Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy*, to Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton T. Reardan.

27. On or about June 9, 2015, the PTO issued U.S. Patent No. 9,050,302 B2 ("the '302 patent") entitled *Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters*, to Mark Eller.

28. Jazz purports and claims to own, and to have the right to enforce, the '431 patent, the '889 patent, the '219 patent, the '506 patent, the '650 patent, the '275 patent, the '203 patent, the '730 patent, the '106 patent, the '107 patent, the '059 patent, the '988 patent, the '182 patent, the '963 patent, the '306 patent, the '619 patent, the '062 patent and the '302 patent (collectively, "the Patents-in-Suit").

29. Jazz Pharmaceuticals, Inc. submitted the '889 patent, the '219 patent, the '730 patent, the '106 patent, the '107 patent, the '506 patent, the '059 patent, the '650 patent, the '275 patent, the '988 patent, the '182 patent, the '963 patent, the '306 patent, the '619 patent, the '062 patent and the '302 patent to the United States Food and Drug Administration ("FDA") for listing, and caused such patents to be listed, in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), in connection with approved New Drug Application ("NDA") No. 21-916 for XYREM® (sodium oxybate) oral solution 500 mg/mL.

30. On or about September 1, 2015, Plaintiffs sued Lupin in this District alleging infringement of the Patents-in-Suit under 35 U.S.C. §§ 271(e)(2)(A), 271(b) and 271(c).

Plaintiffs' Improper Listing of the '730, '106, '107, '059, '988, '182 and '963 Patents in the Orange Book

31. Plaintiffs/Counterclaim-Defendants submitted New Drug Application ("NDA") No. 21-196 for Sodium Oxybate Oral Solution 500 mg/mL to the FDA pursuant to 21 U.S.C. § 355.

32. An applicant for an NDA under 21 U.S.C. § 355(b)(1), must "file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

33. Upon approval, patent numbers and expiration dates, in addition to certain other information on appropriate patents claiming drug products or methods of using such drug products that are the subject of approved applications, will be published daily in the Orange Book.

34. FDA regulations implementing § 355(b)(1) describe the kinds of patents that must be submitted for listing in the Orange Book. Specifically, 21 C.F.R. § 314.53(b)(1) states: "such patents consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. . . . For patents that claim a method of use, the applicant shall submit information only on those patents that claim indications or other conditions of use that are described in the pending or approved application. The applicant shall separately identify each pending or approved method of use and related patent claim. For approved applications, the applicant submitting the method-of-use patent shall identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted."

35. 21 C.F.R. § 314.53(b)(1) also identifies types of patents that must not be submitted for listing in the Orange Book: "Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates are not covered by this section, and information on these patents must not be submitted to FDA."

36. On April 17, 2012, the U.S. Supreme Court issued an Opinion reversing the U.S. Court of Appeals for the Federal Circuit in *Caraco Pharmaceutical Laboratories, Ltd. et al. v. Novo Nordisk A/S et al.*

37. In this decision, the Supreme Court recognized that branded pharmaceutical companies had in the past abused FDA patent listings by including in the listings patents that rightfully did not belong in the listings. "Congress responded to these abuses by creating a mechanism, in the form of a legal counterclaim, for generic manufacturers to challenge patent information a brand has submitted to the FDA."

38. The Supreme Court described the provision as authorizing a "counterclaim seeking an order requiring the [brand] to correct or delete the patent information submitted by the [brand] under subsection (b) or(c) [of §355] on the ground that the patent does not claim either— '(aa) the drug for which the [brand's NDA] was approved; or (bb) an approved method of using the drug.'" 21 U.S.C. § 355(j)(5)(C)(ii)(I).

39. The counterclaim thus enables a generic competitor to obtain a judgment directing a brand to "correct or delete" certain patent information that is blocking the FDA's approval of a generic product.

40. The only relief available for a delisting counterclaim is a court order requiring the FDA to remove or correct the Orange Book listing. 21 U.S.C. § 355(j)(5)(C)(ii)(I); *see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012).

41. The '730, '106, '107, '059, '988, '182 and '963 patents are presently listed in the Orange Book in connection with approved NDA No. 21-196 for XYREM® (sodium oxybate) oral solution 500 mg/mL.

42. Plaintiffs/Counterclaim-Defendants submitted a risk evaluation and mitigation strategy ("REMS") in connection with approved NDA No. 21-196 for XYREM® (sodium oxybate) oral solution 500 mg/mL.

43. Plaintiffs'/Counterclaim-Defendants' submission of the '730, '106, '107, '059, '988, '182 and/or '963 patents for listing in FDA's Orange Book, constitutes an attempt to improperly claim or cover some or all aspects of Plaintiffs' REMS program in connection with approved NDA No. 21-196 for XYREM® (sodium oxybate) oral solution 500 mg/mL pursuant to 21 U.S.C. § 355(b).

Count I
(Declaratory Judgment of Non-Infringement of the '431 patent)

44. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

45. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '431 patent.

46. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '431 patent.

47. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '431 patent.

Count II
(Declaratory Judgment of Non-Infringement of the '889 patent)

48. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

49. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '889 patent.

50. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '889 patent.

51. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '889 patent.

Count III
(Declaratory Judgment of Non-Infringement of the '219 patent)

52. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

53. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '219 patent.

54. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '219 patent.

55. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '219 patent.

Count IV
(Declaratory Judgment of Non-Infringement of the '506 patent)

56. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

57. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '506 patent.

58. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '506 patent.

59. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '506 patent.

Count V
(Declaratory Judgment of Non-Infringement of the '650 patent)

60. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

61. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '650 patent.

62. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '650 patent.

63. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '650 patent.

Count VI
(Declaratory Judgment of Non-Infringement of the '275 patent)

64. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

65. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '275 patent.

66. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '275 patent.

67. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '275 patent.

Count VII
(Declaratory Judgment of Non-Infringement of the '203 patent)

68. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

69. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '203 patent.

70. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '203 patent.

71. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '203 patent.

Count VIII
(Declaratory Judgment of Non-Infringement of the '730 patent)

72. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

73. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '730 patent.

74. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '730 patent.

75. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '730 patent.

Count IX
(Declaratory Judgment of Non-Infringement of the '106 patent)

76. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

77. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '106 patent.

78. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '106 patent.

79. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '106 patent.

Count X
(Declaratory Judgment of Non-Infringement of the '107 patent)

80. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

81. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '107 patent.

82. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '107 patent.

83. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '107 patent.

Count XI
(Declaratory Judgment of Non-Infringement of the '059 patent)

84. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

85. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '059 patent.

86. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '059 patent.

87. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '059 patent.

Count XII
(Declaratory Judgment of Non-Infringement of the '988 patent)

88. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

89. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '988 patent.

90. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '988 patent.

91. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '988 patent.

Count XIII
(Declaratory Judgment of Non-Infringement of the '182 patent)

92. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

93. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '182 patent.

94. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '182 patent.

95. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '182 patent.

Count XIV
(Declaratory Judgment of Non-Infringement of the '963 patent)

96. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

97. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '963 patent.

98. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '963 patent.

99. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '963 patent.

Count XV
(Declaratory Judgment of Non-Infringement of the '306 patent)

100. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

101. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '306 patent.

102. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '306 patent.

103. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '306 patent.

Count XVI
(Declaratory Judgment of Non-Infringement of the '619 patent)

104. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

105. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '619 patent.

106. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '619 patent.

107. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '619 patent.

Count XVII
(Declaratory Judgment of Non-Infringement of the '062 patent)

108. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

109. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '062 patent.

110. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '062 patent.

111. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '062 patent.

Count XVIII
(Declaratory Judgment of Non-Infringement of the '302 patent)

112. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

113. There is an actual, substantial, and continuing justiciable case or controvery regarding non-infringement of the '302 patent.

114. The manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '302 patent.

115. The Court should issue a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the sodium oxybate oral solution products that are the subject of ANDA No. 207415 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '302 patent.

Count XIX
(Declaratory Judgment of Invalidity of the '431 patent)

116. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

117. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '431 patent.

118. The claims of the '431 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

119. The Court should issue a judicial declaration that the claims of the '431 patent are invalid.

Count XX
(Declaratory Judgment of Invalidity of the '889 patent)

120. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

121. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '889 patent.

122. The claims of the '889 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

123. The Court should issue a judicial declaration that the claims of the '889 patent are invalid.

Count XXI
(Declaratory Judgment of Invalidity of the '219 patent)

124. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

125. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '219 patent.

126. The claims of the '219 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

127. The Court should issue a judicial declaration that the claims of the '219 patent are invalid.

Count XXII
(Declaratory Judgment of Invalidity of the '506 patent)

128. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

129. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '506 patent.

130. The claims of the '506 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

131. The Court should issue a judicial declaration that the claims of the '506 patent are invalid.

Count XXIII
(Declaratory Judgment of Invalidity of the '650 patent)

132. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

133. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ‘650 patent.

134. The claims of the ‘650 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

135. The Court should issue a judicial declaration that the claims of the ‘650 patent are invalid.

Count XXIV
(Declaratory Judgment of Invalidity of the ‘275 patent)

136. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

137. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ‘275 patent.

138. The claims of the ‘275 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

139. The Court should issue a judicial declaration that the claims of the ‘275 patent are invalid.

Count XXV
(Declaratory Judgment of Invalidity of the ‘203 patent)

140. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

141. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ‘203 patent.

142. The claims of the ‘203 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

143. The Court should issue a judicial declaration that the claims of the ‘203 patent are invalid.

Count XXVI
(Declaratory Judgment of Invalidity of the ‘730 patent)

144. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

145. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ‘730 patent.

146. The claims of the ‘730 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

147. The Court should issue a judicial declaration that the claims of the ‘730 patent are invalid.

Count XXVII
(Declaratory Judgment of Invalidity of the ‘106 patent)

148. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

149. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ‘106 patent.

150. The claims of the ‘106 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

151. The Court should issue a judicial declaration that the claims of the ‘106 patent are invalid.

Count XXVIII
(Declaratory Judgment of Invalidity of the '107 patent)

152. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

153. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '107 patent.

154. The claims of the '107 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

155. The Court should issue a judicial declaration that the claims of the '107 patent are invalid.

Count XXIX
(Declaratory Judgment of Invalidity of the '059 patent)

156. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

157. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '059 patent.

158. The claims of the '059 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

159. The Court should issue a judicial declaration that the claims of the '059 patent are invalid.

Count XXX
(Declaratory Judgment of Invalidity of the '988 patent)

160. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

161. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '988 patent.

162. The claims of the '988 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

163. The Court should issue a judicial declaration that the claims of the '988 patent are invalid.

Count XXXI
(Declaratory Judgment of Invalidity of the '182 patent)

164. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

165. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '182 patent.

166. The claims of the '182 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

167. The Court should issue a judicial declaration that the claims of the '182 patent are invalid.

Count XXXII
(Declaratory Judgment of Invalidity of the '963 patent)

168. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

169. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '963 patent.

170. The claims of the '963 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

171. The Court should issue a judicial declaration that the claims of the ‘963 patent are invalid.

Count XXXIII
(Declaratory Judgment of Invalidity of the ‘306 patent)

172. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

173. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ‘306 patent.

174. The claims of the ‘306 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

175. The Court should issue a judicial declaration that the claims of the ‘306 patent are invalid.

Count XXXIV
(Declaratory Judgment of Invalidity of the ‘619 patent)

176. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

177. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ‘619 patent.

178. The claims of the ‘619 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

179. The Court should issue a judicial declaration that the claims of the ‘619 patent are invalid.

Count XXXV
(Declaratory Judgment of Invalidity of the '062 patent)

180. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

181. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '062 patent.

182. The claims of the '062 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

183. The Court should issue a judicial declaration that the claims of the '062 patent are invalid.

Count XXXVI
(Declaratory Judgment of Invalidity of the '302 patent)

184. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

185. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '302 patent.

186. The claims of the '302 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

187. The Court should issue a judicial declaration that the claims of the '302 patent are invalid.

Count XXXVII
(Order Requring Removal of the '730 patent from the Orange Book)

188. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

189. The ‘730 patent is directed to a “drug distribution system and method [which] utilizes a central pharmacy and database to track all prescriptions for a sensitive drug.”

190. When a “method of use” patent is submitted to be listed in the FDA’s Orange Book, the applicant must file a Form FDA 3542, entitled “Patent Information Submitted Upon and After Approval of an NDA or Supplement.”

191. Section 4 of Form FDA 3542 is entitled “Method of Use” and requires the applicant to confirm if the patent submitted claims “one or more approved methods of using the approved drug product.”

192. The ‘730 patent does not claim an approved method of using the approved drug product that is the subject of Jazz’s NDA No. 21-196.

193. The ‘730 patent does not claim an approved indication of using the approved drug product that is the subject of Jazz’s NDA No. 21-196.

194. The Court should issue an Order, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I), requiring Plaintiffs/Counterclaim-Defendants to correct or delete the patent information submitted under 21 U.S.C. § 355(b) on the ground that the ‘730 patent does not claim an approved indication or method of using the approved drug product.

Count XXXVIII
(Order Requring Removal of the ‘106 patent from the Orange Book)

195. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

196. The ‘106 patent is directed to a “drug distribution system and method [which] utilizes a central pharmacy and database to track all prescriptions for a sensitive drug.”

197. When a "method of use" patent is submitted to be listed in the FDA's Orange Book, the applicant must file a Form FDA 3542, entitled "Patent Information Submitted Upon and After Approval of an NDA or Supplement."

198. Section 4 of Form FDA 3542 is entitled "Method of Use" and requires the applicant to confirm if the patent submitted claims "one or more approved methods of using the approved drug product."

199. The '106 patent does not claim an approved method of using the approved drug product that is the subject of Jazz's NDA No. 21-196.

200. The '106 patent does not claim an approved indication of using the approved drug product that is the subject of Jazz's NDA No. 21-196.

201. The Court should issue an Order, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I), requiring Plaintiffs/Counterclaim-Defendants to correct or delete the patent information submitted under 21 U.S.C. § 355(b) on the ground that the '106 patent does not claim an approved indication or method of using the approved drug product.

Count XXXIX
(Order Requring Removal of the '107 patent from the Orange Book)

202. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

203. The '107 patent is directed to a "drug distribution system and method [which] utilizes a central pharmacy and database to track all prescriptions for a sensitive drug."

204. When a "method of use" patent is submitted to be listed in the FDA's Orange Book, the applicant must file a Form FDA 3542, entitled "Patent Information Submitted Upon and After Approval of an NDA or Supplement."

205. Section 4 of Form FDA 3542 is entitled "Method of Use" and requires the applicant to confirm if the patent submitted claims "one or more approved methods of using the approved drug product."

206. The '107 patent does not claim an approved method of using the approved drug product that is the subject of Jazz's NDA No. 21-196.

207. The '107 patent does not claim an approved indication of using the approved drug product that is the subject of Jazz's NDA No. 21-196.

208. The Court should issue an Order, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I), requiring Plaintiffs/Counterclaim-Defendants to correct or delete the patent information submitted under 21 U.S.C. § 355(b) on the ground that the '107 patent does not claim an approved indication or method of using the approved drug product.

Count XXXX
(Order Requring Removal of the '059 patent from the Orange Book)

209. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

210. The '059 patent is directed to a "drug distribution system and method [which] utilizes a central pharmacy and database to track all prescriptions for a sensitive drug."

211. When a "method of use" patent is submitted to be listed in the FDA's Orange Book, the applicant must file a Form FDA 3542, entitled "Patent Information Submitted Upon and After Approval of an NDA or Supplement."

212. Section 4 of Form FDA 3542 is entitled "Method of Use" and requires the applicant to confirm if the patent submitted claims "one or more approved methods of using the approved drug product."

213. The ‘059 patent does not claim an approved method of using the approved drug product that is the subject of Jazz’s NDA No. 21-196.

214. The ‘059 patent does not claim an approved indication of using the approved drug product that is the subject of Jazz’s NDA No. 21-196.

215. The Court should issue an Order, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I), requiring Plaintiffs/Counterclaim-Defendants to correct or delete the patent information submitted under 21 U.S.C. § 355(b) on the ground that the ‘059 patent does not claim an approved indication or method of using the approved drug product.

Count XXXXI
(Order Requring Removal of the ‘988 patent from the Orange Book)

216. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

217. The ‘988 patent is directed to a “drug distribution system and method [which] utilizes a central pharmacy and database to track all prescriptions for a sensitive drug.”

218. When a “method of use” patent is submitted to be listed in the FDA’s Orange Book, the applicant must file a Form FDA 3542, entitled “Patent Information Submitted Upon and After Approval of an NDA or Supplement.”

219. Section 4 of Form FDA 3542 is entitled “Method of Use” and requires the applicant to confirm if the patent submitted claims “one or more approved methods of using the approved drug product.”

220. The ‘988 patent does not claim an approved method of using the approved drug product that is the subject of Jazz’s NDA No. 21-196.

221. The ‘988 patent does not claim an approved indication of using the approved drug product that is the subject of Jazz’s NDA No. 21-196.

222. The Court should issue an Order, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I), requiring Plaintiffs/Counterclaim-Defendants to correct or delete the patent information submitted under 21 U.S.C. § 355(b) on the ground that the '988 patent does not claim an approved indication or method of using the approved drug product.

Count XXXXII
(Order Requring Removal of the '182 patent from the Orange Book)

223. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

224. The '182 patent is directed to a "drug distribution system and method [which] utilizes a central pharmacy and database to track all prescriptions for a sensitive drug."

225. When a "method of use" patent is submitted to be listed in the FDA's Orange Book, the applicant must file a Form FDA 3542, entitled "Patent Information Submitted Upon and After Approval of an NDA or Supplement."

226. Section 4 of Form FDA 3542 is entitled "Method of Use" and requires the applicant to confirm if the patent submitted claims "one or more approved methods of using the approved drug product."

227. The '182 patent does not claim an approved method of using the approved drug product that is the subject of Jazz's NDA No. 21-196.

228. The '182 patent does not claim an approved indication of using the approved drug product that is the subject of Jazz's NDA No. 21-196.

229. The Court should issue an Order, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I), requiring Plaintiffs/Counterclaim-Defendants to correct or delete the patent information submitted under 21 U.S.C. § 355(b) on the ground that the '182 patent does not claim an approved indication or method of using the approved drug product.

Count XXXXIII
(Order Requring Removal of the '963 patent from the Orange Book)

230. Lupin re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

231. The '963 patent is directed to a "drug distribution system and method [which] utilizes a central pharmacy and database to track all prescriptions for a sensitive drug."

232. When a "method of use" patent is submitted to be listed in the FDA's Orange Book, the applicant must file a Form FDA 3542, entitled "Patent Information Submitted Upon and After Approval of an NDA or Supplement."

233. Section 4 of Form FDA 3542 is entitled "Method of Use" and requires the applicant to confirm if the patent submitted claims "one or more approved methods of using the approved drug product."

234. The '963 patent does not claim an approved method of using the approved drug product that is the subject of Jazz's NDA No. 21-196.

235. The '963 patent does not claim an approved indication of using the approved drug product that is the subject of Jazz's NDA No. 21-196.

236. The Court should issue an Order, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii)(I), requiring Plaintiffs/Counterclaim-Defendants to correct or delete the patent information submitted under 21 U.S.C. § 355(b) on the ground that the '963 patent does not claim an approved indication or method of using the approved drug product.

* * *

Prayer for Relief

WHEREFORE, Lupin respectfully prays for judgment in its favor and against Plaintiffs:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the sodium oxybate oral solution 500 mg/mL that is the subject of ANDA No. 207415 have not infringed, do not infringe, and will not infringe (either literally or under the doctrine of equivalents) directly or indirectly (either by inducement of contributorily) infringe, any valid or enforceable claim of the Patents-in-Suit;

(a) Declaring that the claims of the Patents-in-Suit are invalid;

(b) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Lupin;

(c) Order requiring the delisting of the '730, '106, '107, '059, '988, '182 and '963 patents from the Orange Book;

(d) Declaring this case exceptional and awarding Lupin its reasonable attorney fees, costs, and expenses in this action under 35 U.S.C. § 285; and

(e) Awarding Lupin any further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Lupin hereby demands a jury trial on all issues so triable.

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.

By: *s/ Melissa E. Flax*

Dated: February 26, 2016

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

On behalf of Defendants Lupin Limited, Lupin Pharmaceuticals, Inc. and Lupin Inc., I hereby certify that the following pending actions are related:

Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc., Civil Action No. 10-6108(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 15-1360(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, Civil Action No. 16-469(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Consolidated Action No. 13-391(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 15-6562(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, Civil Action No. 15-7580(ES) (D.N.J.); *Jazz Pharmaceuticals, Inc. et al. v. Wockhardt Bio AG et al.*, Civil Action No. 16-0099(ES) (D.N.J.); and, *Jazz Pharmaceuticals, Inc. v. Sun Pharmaceuticals Industries Ltd.*, Civil Action No. 15-8229(ES) (D.N.J.).

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 in this jurisdiction, or of any pending arbitration or administrative proceedings.

CARELLA, BYRNE, CECCHI,
OLSTEIN, BRODY & AGNELLO, P.C.

By: *s/ Melissa E. Flax*

Dated: February 26, 2016

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CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendants/Counterclaim-Plaintiffs Lupin Limited, Lupin Pharmaceuticals, Inc. and Lupin Inc. (collectively, "Lupin") hereby certifies that Lupin's counterclaims herein seek injunctive relief and damages, excluding interest, costs and punitive damages, in excess of $150,000. This action is, therefore, not appropriate for compulsory arbitration.

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.

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Dated: February 26, 2016