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

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

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, **Plaintiffs,** **v.** **PAR PHARMACEUTICAL, INC.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Jazz Pharmaceuticals"), by their undersigned attorneys, for their Complaint against defendant Par Pharmaceutical, Inc. ("Par"), allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Par'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 No. 8,772,306 ("the '306 patent" or "the patent-in-suit").

The Parties

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

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

4. On information and belief, defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey.

5. On information and belief, Par develops numerous generic drugs for sale and use throughout the United States, including in this Judicial District. Par has litigated patent cases in this District in the past without contesting personal jurisdiction, and, in at least some of those actions, Par has asserted counterclaims.

Jurisdiction and Venue

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

7. This Court has personal jurisdiction over Par by virtue of, *inter alia,* its systematic and continuous contacts with the State of New Jersey. On information and belief, Par has its principal place of business in Woodcliff Lake, New Jersey, conducts business in this District, purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief,

Par has customers in the State of New Jersey. Further, on information and belief, Par is registered to conduct business in the State of New Jersey.

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

The Patent-In-Suit

9. On July 8, 2014, the United States Patent and Trademark Office ("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 A.

The XYREM® Drug Product

10. 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 '306 patent cover, *inter alia*, methods for treating patients suffering excessive daytime sleepiness, cataplexy, sleep paralysis, apnea, narcolepsy sleep time disturbances, hypnagogic hallucinations, sleep arousal, insomnia and nocturnal myoclonus with GHB or a salt thereof by orally administering an adjusted dosage amount of the salt of GHB when the patient is receiving concomitant administration of valproate. Jazz Pharmaceuticals owns the patent-in-suit.

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

12. The labeling for XYREM® instructs and encourages physicians, other healthcare workers, and patients to administer XYREM® according to the methods claimed in the '306 patent.

Acts Giving Rise to This Suit

13. Pursuant to Section 505 of the FFDCA, Par filed ANDA No. 205403 ("Par's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 500 mg/mL sodium oxybate oral solution ("Par's Proposed Product"), before the patent-in-suit expires.

14. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Par 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) ("Par's Paragraph IV Certification"), alleging that the claims of the '306 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Par's ANDA.

15. No earlier than August 5, 2014, Jazz Pharmaceuticals received written notice of Par's Paragraph IV Certification ("Par's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Par's Notice Letter alleged that the claims of the '306 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Par's ANDA. Par's Notice Letter also informed Jazz Pharmaceuticals that Par seeks approval to market Par's Proposed Product before the patent-in-suit expires.

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

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

Count for Infringement of the '306 Patent

18. Plaintiffs repeat and reallege the allegations of paragraphs 1-17 as though fully set forth herein.

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

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

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

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

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment be entered that Par has infringed the patent-in-suit by submitting ANDA No. 205403;

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

(C) An Order that the effective date of FDA approval of ANDA No. 205403 be a date which is not earlier than the later of the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

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

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Par, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods as claimed in the patent-in-suit, or from actively inducing or contributing to the infringement of any claim of the patent-in-suit, until

after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

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

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

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

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

(J) Costs and expenses in this action; and

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

Dated: October 2, 2014

By: s/ Charles M. Lizza

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

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

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Gabriel P. Brier
Andrew S. Chalson
Frank C. Calvosa
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

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