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Jazz Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**JAZZ PHARMACEUTICALS, INC.,**

**Plaintiff,**

**v.**

**PAR PHARMACEUTICAL, INC.,**

**Defendant.**

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR  
PATENT INFRINGEMENT**

**(Filed Electronically)**

Plaintiff Jazz Pharmaceuticals, Inc. (“Jazz Pharmaceuticals”), by its undersigned attorneys, for its Complaint against defendant Par Pharmaceutical, Inc. (“Par”), alleges 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<sup>®</sup> 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”), and 8,589,182 (the “182 patent”) owned by Jazz Pharmaceuticals (collectively, “the patents-in-suit”).

### **The Parties**

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

3. 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.

4. 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**

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

6. 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.

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

**The Patent-In-Suit**

8. 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” to inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. The ’431 patent was later assigned to Jazz Pharmaceuticals. A copy of the ’431 patent is attached hereto as Exhibit A.

9. 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” to inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. The ’889 patent was later assigned to Jazz Pharmaceuticals. A copy of the ’889 patent is attached hereto as Exhibit B.

10. 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” to inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. The ’219 patent was later assigned to Jazz Pharmaceuticals. A copy of the ’219 patent is attached hereto as Exhibit C.

11. 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” to Jazz Pharmaceuticals as assignee of the inventors Harry Cook,

Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. A copy of the '506 patent is attached hereto as Exhibit D.

12. 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" to Jazz Pharmaceuticals as assignee of the inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. A copy of the '650 patent is attached hereto as Exhibit E.

13. 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" to Jazz Pharmaceuticals as assignee of the inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. A copy of the '275 patent is attached hereto as Exhibit F.

14. 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" to Jazz Pharmaceuticals as assignee of the inventors Harry Cook, Martha Hamilton, Douglas Danielson, Colette Goderstad and Dayton Reardan. A copy of the '203 patent is attached hereto as Exhibit G.

15. On February 23, 2010, the USPTO duly and lawfully issued the '730 patent, entitled "Sensitive Drug Distribution System and Method" to inventors Dayton Reardan, Patti Engle and Bob Gagne. The '730 patent was later assigned to Jazz Pharmaceuticals. A copy of the '730 patent is attached hereto as Exhibit H.

16. On July 27, 2010, the USPTO duly and lawfully issued the '106 patent, entitled "Sensitive Drug Distribution System and Method" to inventors Dayton Reardan, Patti Engle and

Bob Gagne. The '106 patent was later assigned to Jazz Pharmaceuticals. A copy of the '106 patent is attached hereto as Exhibit I.

17. On July 27, 2010, the USPTO duly and lawfully issued the '107 patent, entitled "Sensitive Drug Distribution System and Method" to inventors Dayton Reardan, Patti Engle and Bob Gagne. The '107 patent was later assigned to Jazz Pharmaceuticals. A copy of the '107 patent is attached hereto as Exhibit J.

18. On February 22, 2011, the USPTO duly and lawfully issued the '059 patent, entitled "Sensitive Drug Distribution System and Method" to Jazz Pharmaceuticals as assignee of the inventors Dayton Reardan, Patti Engle and Bob Gagne. A copy of the '059 patent is attached hereto as Exhibit K.

19. On June 4, 2013, the USPTO duly and lawfully issued the '988 patent, entitled "Sensitive Drug Distribution System and Method" to Jazz Pharmaceuticals as assignee of the inventors Dayton Reardan, Patti Engle and Bob Gagne. A copy of the '988 patent is attached hereto as Exhibit L.

20. On November 19, 2013, the USPTO duly and lawfully issued the '182 patent, entitled "Sensitive Drug Distribution System and Method" to Jazz Pharmaceuticals as assignee of the inventors Dayton Reardan, Patti Engle and Bob Gagne. A copy of the '182 patent is attached hereto as Exhibit M.

#### **The XYREM<sup>®</sup> Drug Product**

21. 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<sup>®</sup>. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical compositions containing

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