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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

Plaintiff Jazz Pharmaceuticals Ireland Limited ("Jazz Pharmaceuticals"), by its undersigned attorneys, for its Complaint against Defendants Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. (together, "Lupin" or "Defendants"), 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 Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 215911 ("Lupin's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of Jazz Pharmaceuticals's Xywav® drug products prior to the

expiration of United States Patent Nos. 8,591,922 ("the '922 patent"), 8,772,306 ("the '306 patent"), 8,901,173 ("the '173 patent"), 9,050,302 ("the '302 patent"), 9,132,107 ("the '107 patent"), 9,486,426 ("the '426 patent"), 10,195,168 ("the '168 patent"), 10,213,400 ("the '400 patent"), 10,675,258 ("the '258 patent"), and 10,864,181 ("the '181 patent") (collectively, "the patents-in-suit"), all owned by Jazz Pharmaceuticals.

The Parties

2. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

3. On information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at B/4 Laxmi Towers, Bandra Kurla Complex Bandra (E), Mumbai, 400 051, India, and its registered office at Kalpataru Inspire 3rd Floor, Off Western Express Highway Santacruz (East), Mumbai 400 055, India.

4. On information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having places of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202 and 400 Campus Drive, Somerset, New Jersey 08873.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having places of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202 and 400 Campus Drive, Somerset, New Jersey 08873.

6. On information and belief, Lupin Inc. and Lupin Pharmaceuticals, Inc. are wholly owned subsidiaries of Lupin Ltd.

The Patents-in-Suit

7. On November 26, 2013, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '922 patent, entitled, "Gamma-hydroxybutyrate compositions and their use for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '922 patent is attached hereto as Exhibit A.

8. On July 8, 2014, the USPTO duly and lawfully issued the '306 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '306 patent is attached hereto as Exhibit B.

9. On December 2, 2014, the USPTO duly and lawfully issued the '173 patent, entitled, "Gamma-hydroxybutyrate compositions and their use for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '173 patent is attached hereto as Exhibit C.

10. On June 9, 2015, the USPTO duly and lawfully issued the '302 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '302 patent is attached hereto as Exhibit D.

11. On September 15, 2015, the USPTO duly and lawfully issued the '107 patent, entitled, "Gamma-hydroxybutyrate compositions and their use for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '107 patent is attached hereto as Exhibit E.

12. On November 8, 2016, the USPTO duly and lawfully issued the '426 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '426 patent is attached hereto as Exhibit F.

13. On February 5, 2019, the USPTO duly and lawfully issued the '168 patent, entitled, "Gamma-hydroxybutyrate compositions and their uses for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '168 patent is attached hereto as Exhibit G.

14. On February 26, 2019, the USPTO duly and lawfully issued the '400 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '400 patent is attached hereto as Exhibit H.

15. On June 9, 2020, the USPTO duly and lawfully issued the '258 patent, entitled, "Method of using gamma-hydroxybutyrate compositions for the treatment of disorders," to Jazz Pharmaceuticals as assignee. A copy of the '258 patent is attached hereto as Exhibit I.

16. On December 15, 2020, the USPTO duly and lawfully issued the '181 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '181 patent is attached hereto as Exhibit J.

The Xywav® Drug Product

17. 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 calcium, magnesium, potassium, and sodium oxybates oral solution (NDA No. 212690), which it sells under the trade name Xywav®. The claims of the patents-in-suit cover, *inter alia*, methods of use and administration of calcium, magnesium, potassium, and sodium oxybates, or pharmaceutical compositions containing calcium, magnesium, potassium, and sodium oxybates.

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

19. The labeling for Xywav® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Xywav® for the treatment of cataplexy or excessive daytime sleepiness in patients with narcolepsy .

20. The labeling for Xywav® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to modify the dose of Xywav® for patients receiving calcium, magnesium, potassium, and sodium oxybates when divalproex sodium (valproate) is concomitantly administered.

21. The labeling for Xywav® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Xywav® according to one or more of the methods claimed in the patents-in-suit.

Acts Giving Rise To This Suit

22. Pursuant to Section 505 of the FFDCA, Lupin submitted Lupin's ANDA seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of 0.5 g/mL calcium, magnesium, potassium, and sodium oxybates oral solution ("Lupin's Proposed Product") before the patents-in-suit expire.

23. On information and belief, following FDA approval of Lupin's ANDA, Lupin will make, use, sell, or offer to sell Lupin's Proposed Product throughout the United States, or import such generic products into the United States.

24. On information and belief, in connection with the submission of Lupin's ANDA as described above, Lupin provided written certifications to the FDA pursuant to Section 505 of

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