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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.	Honorable Stanley R. Chesler, U.S.D.J. Civil Action No. 24 CV 8786 (SRC)(JSA) **DEFENDANTS' ANSWER TO THE COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendants Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") by and through the undersigned attorneys, answer the Complaint of Jazz Pharmaceuticals Ireland Limited ("Jazz Pharmaceuticals" or "Plaintiff") as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Lupin denies all allegations in Plaintiff's Complaint except those specifically admitted below.

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' Xywav® drug products prior to the expiration of United States Patent No. 11,986,446 ("the '446 patent" or "the patent-in-suit"), owned by Jazz Pharmaceuticals.

RESPONSE: Lupin admits that Plaintiff's Complaint against Lupin is for infringement of U.S. Patent No. 11,986,446 ("the '446 patent" or "the patent-in-suit") arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., but denies that Plaintiff is entitled to any such relief. Lupin further admits that it submitted Abbreviated New Drug Application ("ANDA") No. 215911 ("Lupin's ANDA") seeking U.S. Food and Drug Administration ("FDA") approval for a proposed generic calcium, magnesium, potassium, and sodium oxybate oral solution ("Lupin's Proposed Product"), which Plaintiff markets as Xywav®, prior to the expiration of the patent-in-suit. Lupin also admits that the face of the patent-in-suit lists Jazz Pharmaceuticals Ireland Limited as the assignee. Lupin denies any remaining allegations in this paragraph.

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.

RESPONSE: On information and belief, Lupin admits that Plaintiff Jazz Pharmaceuticals Ireland Limited is a company organized and existing under the laws of Ireland. Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

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.

RESPONSE: Lupin admits that Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra Kurla Complex Bandra (E), Mumbai, 400 051, India.

Lupin denies that Lupin Ltd. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

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.

RESPONSE: Lupin admits that Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 5801 Pelican Bay Blvd., Suite 500, Naples, Florida 34108. Lupin denies any remaining allegations in this paragraph.

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.

RESPONSE: Lupin admits that Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 5801 Pelican Bay Blvd., Suite 500, Naples, Florida 34108. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

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

RESPONSE: Lupin admits that Lupin Inc. and Lupin Pharmaceuticals, Inc. are direct or indirect wholly owned subsidiaries of Lupin Ltd. Further, Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

THE PATENT-IN-SUIT

7. On May 21, 2024, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '446 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," to Jazz Pharmaceuticals as assignee. A copy of the '446 patent is attached hereto as Exhibit A.

RESPONSE: Lupin admits that Plaintiff purports to attach a copy of the '446 patent to the Complaint as Exhibit A. Lupin further admits that the face of the '446 patent indicates that it issued on May 21, 2024 and is titled "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," but specifically denies that the patent was duly and lawfully issued. Lupin also admits that the face of '446 patent lists Jazz Pharmaceuticals Ireland Limited as an assignee. Lupin denies any remaining allegations in this paragraph.

THE XYWAV® DRUG PRODUCT

8. 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 patent-in-suit cover, *inter alia*, methods of use and administration of calcium, magnesium, potassium, and sodium oxybates.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that the FDA's website "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") currently lists Jazz Pharmaceuticals as the holder of NDA No. 212690 for 0.5 g/mL calcium, magnesium, potassium, and sodium oxybates oral solution, which is sold as Xywav®. Lupin denies any remaining allegations in this paragraph.

9. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '446 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Xywav®.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that the FDA's website indicates that the patent-in-suit is listed in the Orange Book with respect to Xywav®. Lupin denies any remaining allegations in this paragraph.

10. 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.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin only admits that the labeling on the FDA's website lists the indications and usage for Xywav® and states, "XYWAV is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy." Lupin denies any remaining allegations in this paragraph.

11. 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.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin only admits that the labeling available on the FDA's website states "Concomitant use with divalproex sodium: An initial reduction in XYWAV dose of at least 20% is recommended." Lupin denies any remaining allegations in this paragraph.

12. 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 '446 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin only admits that the labeling on the FDA's website lists the indications and usage for Xywav® and states, "XYWAV is a central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy." Lupin denies any remaining allegations in this paragraph.

JURISDICTION AND VENUE

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that this action cites the patent laws of the United States generally. Lupin does not contest that this Court has jurisdiction over the subject matter of this action against Lupin Inc. for the purposes of the asserted patent in this action only. Lupin denies any remaining allegations in this paragraph.

14. On information and belief, Lupin Ltd. derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

RESPONSE: Lupin admits that Lupin Ltd. is in the business of developing, preparing, and manufacturing generic drugs. Lupin further admits that Lupin Pharmaceuticals, Inc. sells and distributes generic drugs throughout the United States, including within the State of New Jersey. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties of this action. Lupin denies any remaining allegations in this paragraph.

15. This Court has personal jurisdiction over Lupin Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, Lupin Inc. and Lupin Pharmaceuticals, Inc., companies with a regular and established place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Lupin Inc. and Lupin Pharmaceuticals, Inc.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that this Court has personal jurisdiction over Lupin Ltd. for purposes of this action only. Lupin denies any remaining allegations in this paragraph.

16. On information and belief, Lupin Inc. derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

RESPONSE: Denied.

17. This Court has personal jurisdiction over Lupin Inc. because, *inter alia*, it: (1) on information and belief, maintains a regular and established, physical place of business at 400 Campus Drive, Somerset, New Jersey 08873; (2) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Lupin Pharmaceuticals, Inc., a company with a regular and established place of business in New Jersey; and (3) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Lupin Pharmaceuticals, Inc. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Lupin Inc. On information and belief, Lupin Inc. purposefully has conducted and continues to conduct business in this Judicial District.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that this Court has jurisdiction over the subject matter of this action against Lupin Inc. for the purposes of the asserted patent in this action only. Lupin denies any remaining allegations in this paragraph.

18. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Lupin Pharmaceuticals, Inc. maintains a regular and established, physical place of business at 400 Campus Drive, Somerset, New Jersey 08873. On information and belief, Lupin Pharmaceuticals, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0101043376. On information and belief, Lupin Pharmaceuticals, Inc. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005159. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. On information and belief, Lupin Pharmaceuticals, Inc. purposefully has conducted and continues to conduct business in this Judicial District.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Pharmaceuticals, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0101043376. Lupin further admits that Lupin Pharmaceuticals, Inc. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005159. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

19. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. are in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. also prepare and/or aid in the preparation and submission of ANDAs to the FDA, including Lupin's ANDA.

RESPONSE: Lupin admits that Lupin Ltd. is in the business of developing, preparing, and manufacturing generic drugs. Lupin further admits that Lupin Pharmaceuticals, Inc. sells and distributes generic drugs throughout the United States, including within the State of New Jersey. Lupin admits that Lupin Inc. prepared and submitted the Lupin ANDA to the FDA. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

20. On information and belief, this Judicial District is a likely destination for the generic drug products described in Lupin's ANDA.

RESPONSE: Lupin admits that Lupin Inc. submitted the Lupin ANDA to the FDA seeking approval for Lupin's Proposed Product. Lupin denies any remaining allegations of this paragraph.

21. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. derive substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

RESPONSE: Lupin admits that Lupin Ltd. is in the business of developing, preparing, and manufacturing generic drugs. Lupin further admits that Lupin Pharmaceuticals, Inc. sells and distributes generic drugs throughout the United States, including within the State of New Jersey. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

22. This Court also has personal jurisdiction over Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. because, *inter alia*, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2). On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. intend a future course of conduct that includes acts of patent infringement

in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Jazz Pharmaceuticals in New Jersey and in this Judicial District.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that this Court has personal jurisdiction against Lupin Inc. for the purposes of this action only. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

23. In the alternative, this Court has personal jurisdiction over Lupin Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Jazz Pharmaceuticals' claims arise under federal law; (b) Lupin Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that this Court has personal jurisdiction for the purposes of this action only. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

24. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. work in privity and/or concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

RESPONSE: Lupin admits that Lupin Inc. and Lupin Pharmaceuticals, Inc. are direct or indirect wholly owned subsidiaries of Lupin Ltd. Lupin further admits that Lupin Ltd. is in the business of developing, preparing, and manufacturing generic drugs. Lupin further admits that Lupin Pharmaceuticals, Inc. sells and distributes generic drugs throughout the United States,

including within the State of New Jersey. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

25. On information and belief, each of Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. actively participated in the submission of Lupin's ANDA. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will work in privity and/or concert with one another and/or other related entities towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including the proposed product described in Lupin's ANDA, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patent-in-suit.

RESPONSE: Lupin admits that Lupin Inc. prepared and submitted the Lupin ANDA to the FDA. Lupin further admits that Lupin Ltd. is in the business of developing, preparing, and manufacturing generic drugs. Lupin further admits that Lupin Pharmaceuticals, Inc. sells and distributes generic drugs throughout the United States, including within the State of New Jersey. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

26. On information and belief, Lupin Ltd. intends to benefit directly if Lupin's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Lupin's ANDA.

RESPONSE: Lupin admits that Lupin Inc. prepared and submitted the Lupin ANDA to the FDA seeking approval for Lupin's Proposed Product. Lupin denies that Lupin Ltd. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

27. On information and belief, Lupin Inc. intends to benefit directly if Lupin's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Lupin's ANDA.

RESPONSE: Lupin admits that Lupin Inc. submitted the Lupin ANDA to the FDA seeking approval of Lupin's Proposed Product. Lupin denies any remaining allegations in this paragraph.

28. On information and belief, Lupin Pharmaceuticals, Inc. intends to benefit directly if Lupin's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of Lupin's ANDA.

RESPONSE: Lupin admits that Lupin Inc. submitted the Lupin ANDA to the FDA seeking approval of Lupin's Proposed Product. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

29. On information and belief, Lupin Inc. and Lupin Pharmaceuticals, Inc. act at the direction, and for the benefit, of Lupin Ltd. and are controlled and/or dominated by Lupin Ltd.

RESPONSE: Lupin admits that Lupin Inc. and Lupin Pharmaceuticals, Inc. are direct or indirect wholly owned subsidiaries of Lupin Ltd. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

30. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. act, operate, and/or hold themselves out to the public as a single integrated business.

RESPONSE: Lupin admits that Lupin Inc. and Lupin Pharmaceuticals, Inc. are direct or indirect wholly owned subsidiaries of Lupin Ltd. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

31. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. 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 Laboratories 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.); *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.); *Jazz Pharmaceuticals, Inc., et al. v. Lupin Ltd., et al.*, Civ. Action No. 2:15-cv-06548 (ES)(JAD) (D.N.J.); *Horizon Pharma Ireland Limited, et al. v. Lupin Ltd., et al.*, Civ. Action No. 1:15-cv-06935 (NLH)(AMD) (D.N.J.); *Senju Pharmaceutical Co., Ltd, et al. v. Lupin Ltd., et al.*, Civ. Action No. 1:16-cv-01097 (JBS)(KMW) (D.N.J.); *Bausch Health Ireland Ltd., et al. v. Lupin Ltd., et al.*, 1:20-cv-11039 (RMB)(KMW) (D.N.J.); *Merck Sharp & Dohme BV, et al. v.*

Lupin Ltd., et al., 2:20-cv-02786 (CCC)(MF) (D.N.J.); *Bristol-Myers Squibb Co. v. Lupin Ltd., et al.*, 3:20-cv-07810 (MAS)(TJB) (D.N.J.); *Jazz Pharmaceuticals Ireland Ltd. v. Lupin Ltd., et al.*, Civ. Action No. 2:21-cv-14271 (SRC)(JSA) (D.N.J.); *Jazz Pharmaceuticals Ireland Ltd. v. Lupin Ltd., et al.*, Civ. Action No. 2:22-cv-02773 (SRC)(JSA) (D.N.J.); and *Jazz Pharmaceuticals Ireland Ltd. v. Lupin Ltd., et al.*, Civ. Action No. 2:23-cv-00329 (SRC)(JSA) (D.N.J.).

RESPONSE: Lupin admits that Lupin has not contested jurisdiction in the District of New Jersey in one or more prior cases arising from the filing of its ANDAs and that it filed counterclaims in those cases. However, Lupin expressly denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that venue is proper for the purposes of this action only. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc. are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

ACTS GIVING RISE TO THIS SUIT

33. 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 patent-in-suit expires.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Inc. submitted the Lupin ANDA to the FDA seeking approval for Lupin's Proposed Product prior to the expiration of the patent-in-suit. Lupin denies any remaining allegations in this paragraph.

34. 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.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Inc. submitted the Lupin ANDA to the FDA seeking approval for Lupin's Proposed Product. Lupin denies any remaining allegations in this paragraph.

35. On information and belief, in connection with the submission of Lupin's ANDA as described above, Lupin provided written certification to the FDA pursuant to 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 '446 patent are invalid and/or will not be infringed by the activities described in Lupin's ANDA.

RESPONSE: Admitted.

36. No earlier than July 17, 2024, Lupin sent notice of its Paragraph IV Certification to Jazz Pharmaceuticals ("Lupin's Notice Letter"). Lupin's Notice Letter alleged that the claims of the '446 patent are invalid 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 expiration of the '446 patent.

RESPONSE: Lupin admits that it sent letters to Plaintiff on or about July 17, 2024, that provided written notice of Lupin's ANDA and Paragraph IV Certification and included a statement of the factual and legal bases for stating that the asserted patent is invalid, is unenforceable, and/or will not be infringed by Lupin's Proposed Product. Lupin also admits that Lupin's Notice Letter also informed Jazz Pharmaceuticals that Lupin seeks approval of Lupin's Proposed Product before the patent-in-suit expires. Lupin denies any remaining allegations in this paragraph.

COUNT FOR INFRINGEMENT OF THE '446 PATENT

37. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

RESPONSE: Lupin repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

38. Lupin's submission of Lupin's ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Lupin's Proposed Product, prior to the expiration of the '446 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

39. There is a justiciable controversy between the parties hereto as to the infringement of the '446 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Plaintiff has filed suit accusing Lupin of infringing the '446 patent. Lupin denies any remaining allegations in this paragraph.

40. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will infringe one or more claims of the '446 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

41. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will induce infringement of one or more claims of the '446 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will intentionally encourage acts of direct infringement with knowledge of the '446 patent and knowledge that their acts are encouraging infringement.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

42. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. will contributorily infringe one or more claims of the '446 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in or for the United States. On information and belief, Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc. have had and continue to have knowledge that Lupin's Proposed Product is especially adapted for a use that infringes one or more claims of the '446 patent and that there is no substantial non-infringing use for Lupin's Proposed Product.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

43. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Lupin Ltd., Lupin Inc., and Lupin Pharmaceuticals, Inc.'s infringement of the '446 patent is not enjoined.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

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

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

45. 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.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

PRAYER FOR RELIEF

Lupin denies that Plaintiff is entitled to any of the relief requested in its Prayer for Relief or to any relief whatsoever, including the relief specifically requested against Lupin.

LUPIN'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Lupin asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Lupin reserves the right to amend this Answer with additional defenses as further information is obtained in discovery. Lupin asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(Invalidity)

The ’446 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 or under other judicially created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE
(No Direct Infringement)

Lupin does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’446 patent. If the product that is the subject of ANDA No. 215911 were marketed, Lupin would not infringe any valid and enforceable claim of the ’446 patent.

THIRD AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Lupin has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the ’446 patent. If the product that is the subject of ANDA No. 215911 were marketed, Lupin would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the ’446 patent.

FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Lupin.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Lupin for an exceptional case under 35 U.S.C. § 285.

SIXTH AFFIRMATIVE DEFENSE

Lupin has not willfully infringed any claim of the ’446 patent.

SEVENTH AFFIRMATIVE DEFENSE

Lupin Pharmaceuticals, Inc. is not a proper party to this action.

EIGHTH AFFIRMATIVE DEFENSE

Lupin Ltd. is not a proper party to this action.

NINTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Lupin respectfully requests that Plaintiff take nothing by way of its Complaint, that judgment be entered in favor of Lupin, and that Lupin be awarded its attorneys' fees and costs and all other just and proper relief.

LUPIN INC.'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

For its counterclaims against Jazz Pharmaceuticals Ireland Limited ("Counterclaim Defendant" or "Jazz Pharmaceuticals"), Defendant Lupin Inc. ("Counterclaim Plaintiff" or "Lupin Inc.") states as follows:

PARTIES

1. Upon information and belief, Jazz Pharmaceuticals 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.

2. Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 5801 Pelican Bay Blvd., Suite 500, Naples, Florida 34108.

JURISDICTION AND VENUE

3. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

4. This Court has personal jurisdiction over Counterclaim Defendant on the basis of, *inter alia*, its contacts with New Jersey relating to the subject matter of this action, including having filed suit.

BACKGROUND

5. Upon information and belief, Jazz Pharmaceuticals holds approved New Drug Application ("NDA") No. 212690 for Xywav®, which contains the active ingredients 0.5 g/mL calcium, magnesium, potassium, and sodium oxybates oral solution.

6. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

7. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

8. U.S. Patent No. 11,986,446 ("the '446 patent"), titled "Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters," was issued on May 21, 2024.

9. Upon information and belief, Jazz Pharmaceuticals is the assignee of the '446 patent.

10. Upon information and belief, Jazz Pharmaceuticals caused the '446 patent to be listed in the Orange Book as a patent that claims a pharmaceutical composition comprising and/or a method of using such a drug for which Jazz Pharmaceuticals submitted NDA No. 212690.

11. Lupin Inc. submitted Abbreviated New Drug Application ("ANDA") No. 215911 to obtain FDA approval of 0.5 g/mL calcium, magnesium, potassium, and sodium oxybates oral solution ("Lupin Inc.'s ANDA Product") prior to the expiration of the '446 patent.

12. Lupin Inc.'s ANDA No. 215911 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '446 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lupin Inc.'s ANDA Product.

13. On August 27, 2024, Counterclaim Defendant filed the instant lawsuit alleging infringement of the '446 patent.

COUNT I
(Declaratory Judgment of Non-Infringement of the '446 Patent)

14. Lupin Inc. realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

15. Jazz Pharmaceuticals alleges ownership of the '446 patent, and Jazz Pharmaceuticals has brought claims against Lupin Inc. alleging infringement of the '446 patent.

16. The manufacture, use, or sale of Lupin Inc.'s ANDA Products would not infringe any valid or enforceable claim of the '446 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

17. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin Inc.'s ANDA No. 215911 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '446 patent.

18. Lupin Inc. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '446 patent and is not liable for such infringement.

19. Lupin Inc. is entitled to a declaration that the manufacture, use, or sale of its ANDA Product would not infringe any valid or enforceable claim of the '446 patent.

COUNT II
(Declaratory Judgment of Invalidity or Unenforceability of the '446 Patent)

20. Lupin Inc. realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

21. Jazz Pharmaceuticals alleges ownership of the '446 patent, and Jazz Pharmaceuticals has brought claims against Lupin Inc. alleging infringement of the '446 patent.

22. One of more claims of the '446 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or under other judicially created bases for invalidation and/or in view of defenses recognized in 35 U.S.C. § 282(b).

23. The '446 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

24. The alleged invention of the '446 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '446 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '446 patent and would have had a reasonable expectation of success in doing so.

25. The subject matter claimed in the '446 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was

made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

26. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin Inc.'s ANDA No. 215911 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '446 patent.

27. Lupin Inc. is entitled to a declaration that all claims of the '446 patent are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or under other judicially created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, Lupin Inc. requests judgment in its favor and against Counterclaim Defendant as follows:

a. Declaring that all claims of the '446 patent are invalid;

b. Declaring that the filing of Lupin Inc.'s ANDA No. 215911 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '446 patent;

c. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Products does not, and would not, if marketed, infringe any valid and enforceable claim of the '446 patent;

d. Declaring this an exceptional case in favor of Lupin Inc. and awarding its attorneys' fees pursuant to 35 U.S.C. § 285;

e. Awarding costs and expenses; and

f. Awarding any and all such other relief as the Court determines to be just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendants, Lupin Ltd., Lupin Inc. and Lupin Pharmaceuticals, Inc.

By: *s/ James S. Richter*
James S. Richter
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Dated: October 9, 2024

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Defendants certifies that, to the best of his knowledge, information and belief, the matter in controversy involves the same plaintiff, the same ANDA, and some of the same defendants as the matter captioned *Jazz Pharmaceuticals Ireland Limited v. Lupin Inc., et al.*, Civil Action No. 21-14271 (SRC)(JSA) (D.N.J.) (consolidated).

To the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any other pending arbitration or administrative proceeding.

s/ *James S. Richter*
James S. Richter

Dated: October 9, 2024

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants, by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: October 9, 2024

CERTIFICATION OF SERVICE

The undersigned attorney certifies that a copy of the foregoing Answer, Affirmative Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on October 9, 2024.

s/ James S. Richter
James S. Richter

Dated: October 9, 2024