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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TARO PHARMACEUTICALS U.S.A., INC.
and TARO PHARMACEUTICALS NORTH
AMERICA, INC.

Plaintiffs,

C.A. No. ____

v.

LUPIN LIMITED, LUPIN
PHARMACEUTICALS, INC., and LUPIN
ATLANTIS HOLDING SA,

Defendants.

**PLAINTIFFS TARO PHARMACEUTICALS U.S.A., INC. AND TARO
PHARMACEUTICALS NORTH AMERICA, INC.'S COMPLAINT
AGAINST LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., AND
LUPIN ATLANTIS HOLDING SA**

Plaintiffs Taro Pharmaceuticals U.S.A., Inc. ("Taro USA") and Taro Pharmaceuticals North America, Inc. ("Taro North Am.") (together, "Taro" or "Plaintiffs") for its complaint against defendants, Lupin Limited ("Lupin Ltd."), Lupin Pharmaceuticals, Inc. ("LPI"), and Lupin

Atlantis Holding SA (“Lupin Atlantis”) (collectively, “Lupin” or “Defendants”), to the best of its knowledge, information and belief, allege as follows:

NATURE OF THE ACTION

1. This is an action under 35 U.S.C. § 271, *et. seq.*, for infringement of United States Patent Nos. 8,277,780 (the “780 patent”) (attached as ***Exhibit A***) and 8,715,624 (the “624 patent,”) (attached as ***Exhibit B***), relating to Taro’s commercially successful product, Topicort® (desoximetasone) Topical Spray, 0.25%. This action arises from Lupin’s filing of a supplemental Abbreviated New Drug Application with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of Topicort® (desoximetasone) Topical Spray, 0.25% prior to the latest of the expiration dates of the patents-in-suit.

THE PARTIES

2. Taro USA is a company organized and existing under the laws of the State of New York, with a principal place of business at 3 Skyline Drive, Hawthorne, New York 10532.

3. Taro North Am. is a company organized and existing under the laws of the Cayman Islands, with a principal place of business at 103 South Church Street, Grand Cayman, Cayman Islands.

4. On information and belief, Defendant Lupin Ltd. is a corporation operating and existing under the laws of India, having a principal 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 400055, India. Lupin Ltd. is one of the largest generic pharmaceutical companies in terms of global revenue.

5. On information and belief, LPI is a corporation operating and existing under the laws of Delaware, having a place of business at 111 South Calvert Street, 21st Floor, Baltimore MD 21202.

6. On information and belief, LPI is a wholly owned subsidiary of Lupin Ltd.

7. LPI manufactures, sells, markets, and distributes generic pharmaceutical products throughout the United States, including in this district, in conjunction with or under the direction of Lupin Ltd. On information and belief, Lupin Ltd. has previously designated LPI as its US agent for other ANDA submissions.

8. On information and belief, Lupin Atlantis is a corporation organized and existing under the laws of Switzerland, having its principal place of business at Landis + Gyr-Strasse 1, 6300 Zug, Switzerland.

9. On information and belief, Lupin Atlantis is a wholly owned subsidiary of Lupin Ltd.

10. On information and belief, Lupin has engaged in conduct that reliably predicts New Jersey activities. By submitting ANDA No. 208124/S-004, Lupin has taken the significant step of applying to FDA for approval to manufacture, sell, offer to sell, and/or import its generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml in the United States, including in this district.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* Based on the facts alleged herein, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338, and has personal jurisdiction over both Lupin Ltd. and LPI.

12. On information and belief, Lupin Ltd. directed its agents LPI and Lupin Atlantis to participate and collaborate in the research and development of the proposed generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml and in the preparation and filing of ANDA No. 208124/S-004.

13. On information and belief, Lupin sought FDA approval because it intended to commit acts of patent infringement under 35 U.S.C. § 271(a), (b), and (c) through its manufacture, use, sell, and offer for sale of its generic Desoximetasone Topical Spray, 0.25% in New Jersey.

14. This Court has personal jurisdiction over Lupin. Lupin avails itself of the benefits and protections of the laws of the State of New Jersey. For example, LPI is registered to do business in the State of New Jersey under Business ID Number 0100953673, and LPI is registered with the State of New Jersey as a manufacturer and wholesale distributor of drugs under Registration Numbers 5004060 and 5005159.

15. This Court also has personal jurisdiction over Lupin by virtue of its systematic and continuous contacts with the State of New Jersey. On information and belief, Lupin Ltd., LPI, Lupin Atlantis, and their affiliates manufacture generic pharmaceuticals at a facility located at 400 Campus Drive, Somerset, NJ. Lupin Ltd., LPI, and Lupin Atlantis sell, offer for sale, and distribute generic pharmaceuticals throughout the State of New Jersey.

16. On information and belief, Lupin has at all relevant times maintained continuous and systematic contacts with the State of New Jersey, including but not limited to, its aforementioned business of preparing generic pharmaceuticals that Lupin distributes throughout the United States.

17. Lupin has previously availed themselves of the jurisdiction of this Court by filing suit in this district, consenting to jurisdiction in this district, and/or asserting counterclaims in at

least the following civil actions initiated in this district: *Lupin Ltd., et al. v. Merck, Sharp & Dohme Corp.*, Civil Action No. 3:10-cv-00683; *Senju Pharmaceutical Co., Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 1:15-cv-00335; *Senju Pharmaceutical Co., Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 1:14-cv-05144; *Janssen Products, L.P., et al. v. Lupin Ltd., et al.*, Civil Action No. 2:14-cv-01370; *Takeda Pharmaceutical Co. Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 3:12-cv-07333; *AstraZeneca Pharmaceuticals LP, et al. v. Lupin Ltd., et al.*, Civil Action No. 3:12-cv-06888; *Otsuka Pharmaceutical Co., Ltd. v. Lupin Ltd., et al.*, Civil Action No. 1:14-cv-07104; and *Prime European Therapeutics, S.p.A. v. Novel Labs., Inc., et al.*, Civil Action No. 3:17-cv-01944; *Taro Pharmaceuticals USA, Inc., et al. v. Lupin Ltd., et al.*, Civil Action No. 2:18-cv-04225-JMV-MF.

18. Venue is proper in this district under 28 U.S.C. §1400(b) because Lupin “committed an act of infringement” in this district and has a “regular place and established place of business” in this district. Lupin submitted ANDA No. 208124/S-004 pursuant to 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (“FFDCA”), and upon receiving approval of ANDA No. 208124/S-004, will manufacture, sell, offer to sell, and/or import its proposed generic Desoximetasone Topical Spray, 0.25%, 30 ml, 50 ml, and 100 ml throughout the United States, including in this district. Thus, Lupin has committed an act of infringement in this district. Lupin also has a “regular and established place of business” at its 150,000-square-foot facility at 400 Campus Drive, Somerset, New Jersey where Lupin manufacturers about 3.5 billion standard units of pharmaceutical products.

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