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

ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC.

Plaintiffs,

-v-

LUPIN LTD. and  
LUPIN PHARMACEUTICALS, INC.,

Defendant.

**DOCUMENT FILED  
ELECTRONICALLY**

Civ. Action No. 2:10-cv-00322 (SRC) (MAS)

**ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS  
OF DEFENDANTS LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.**

Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by Plaintiffs Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMJPI"), as follows:

**The Parties**

1. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 and therefore denies such allegations..
2. Lupin Pharmaceuticals, Inc. admits that it is a corporation organized under the laws of Virginia, having its principal place of business at Harborplace Tower, 111 South Calvert

Street, Baltimore, Maryland 21202 and is registered to do business in New Jersey and has appointed the National Registered Agents Inc. of Princeton, New Jersey as its registered agent in New Jersey for service of process. Lupin Pharmaceuticals, Inc. further admits that it is a wholly owned subsidiary of Lupin Ltd. Lupin denies the remaining allegations in paragraph 2.

3. Lupin Ltd. admits that it is an Indian corporation having a place of business at Laxmi Towers, "B" Wing, 5<sup>th</sup> Floor, Bandra Kurla Complex, Mumbai, 400 051, India. Lupin Ltd. further admits that it manufactures generic drugs for sale and use in the United States, including in this judicial district. Lupin denies the remaining allegations in paragraph 3.

4. Lupin admits that Lupin Ltd. holds various Abbreviated New Drug Applications on file at the U.S. Food and Drug Administration ("FDA"). Lupin further admits that Lupin Ltd. manufactures generic drugs for sale and use in the United States, including in this judicial district. Lupin denies the remaining allegations in paragraph 4.

#### **Jurisdiction and Venue**

5. Lupin admits that this action arises under the patent laws of the United States.

6. Lupin admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. For the purposes of this action only, Lupin Ltd. and Lupin Pharmaceuticals, Inc. do not contest personal jurisdiction, but deny the remaining allegations in paragraph 7 of the Complaint.

8. For the purposes of this action only, Lupin Ltd. and Lupin Pharmaceuticals, Inc. do not contest personal jurisdiction, but deny the remaining allegations in paragraph 8 of the Complaint.

9. For the purposes of this action only, Lupin Ltd. and Lupin Pharmaceuticals, Inc. do not contest personal jurisdiction, but deny the remaining allegations in paragraph 9 of the Complaint.

10. For the purposes of this action only, Lupin Ltd. and Lupin Pharmaceuticals, Inc. do not contest personal jurisdiction, but deny the remaining allegations in paragraph 10 of the Complaint.

11. For the purposes of this action only, Lupin does not contest venue in this judicial district and otherwise denies the allegations of paragraph 11 of the Complaint.

**Count 1: Patent Infringement**

12. Lupin re-asserts its responses to paragraphs 1-11 as if fully set forth herein.

13. Lupin admits that the '815 patent was issued by the U.S. Patent and Trademark Office ("USPTO") on April 10, 2001, is entitled "Triphasic Oral Contraceptive," is assigned on its face to Ortho-McNeil Pharmaceuticals, Inc., and what purports to be a copy of the '815 patent is attached to the Complaint as Exhibit A. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 13 of the Complaint and, therefore, denies them.

14. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14 of the Complaint and, therefore, denies them.

15. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 15 of the Complaint and, therefore, denies them.

16. Lupin admits that Lupin Ltd. submitted Abbreviated New Drug Application ("ANDA") No. 200541 to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell norgestimate and ethinyl estradiol tablets (0.180 mg/0.025 mg, 0.215 mg/0.025 mg,

0.250 mg/0.025 mg) before the expiration of the '815 patent term on December 9, 2019. Lupin denies the remaining allegations in paragraph 16.

17. Lupin admits that Lupin Ltd. submitted ANDA No. 200541 to the FDA, pursuant to 21 U.S.C. § 355(j), and that ANDA 200541 contains a Paragraph IV certification with respect to the '815 patent, which certification asserts that this patent is invalid and/or will not be infringed by Lupin's norgestimate and ethinyl estradiol tablets (0.180 mg/0.025 mg, 0.215 mg/0.025 mg, 0.250 mg/0.025 mg). Lupin denies the remaining allegations in paragraph 17.

18. Lupin admits the allegations in paragraph 18 of the Complaint.

19. Lupin admits that Lupin Ltd. is subject to 35 U.S.C. § 271(e)(2)(A) as a result of Lupin Ltd.'s filing ANDA 200541. Lupin denies the remaining allegations of paragraph 19.

20. Lupin denies the allegations of paragraph 20 of the Complaint.

21. Lupin denies the allegations of paragraph 21 of the Complaint.

22. Lupin denies the allegations in paragraph 22 of the Complaint.

23. Lupin denies the allegations in paragraph 23 of the Complaint.

#### **Prayer For Relief**

Lupin denies that plaintiffs are entitled to the judgment and relief requested in the Prayer for Relief set forth in the Complaint.

#### **Affirmative and Separate Defenses**

Without prejudice to the denials set forth in its responses to paragraphs 1 through 23 of the Complaint, Lupin alleges the following Affirmative and Separate Defenses to the Complaint.

#### **First Affirmative and Separate Defense (Invalidity of the '815 Patent)**

24. The '815 patent, and each of the claims 1 through 4 thereof, are invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

**Counterclaims**

25. Defendant/Counterclaim-Plaintiffs Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin”) bring the following Counterclaims against Plaintiffs/Counterclaim-Defendants Ortho-McNeil-Janssen Pharmaceuticals, Inc. (collectively, “OMJPI”) for a declaratory judgment that the ’815 patent is invalid.

**The Parties**

26. Counterclaim-Plaintiff Lupin Ltd. is a corporation organized and existing under the laws of India having a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

27. Counterclaim-Plaintiff Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Virginia, having a principal place of business at 111 S. Calvert Street, Suite 2150, Baltimore, Maryland.

28. Upon information and belief, Counterclaim-Defendant OMJPI is a corporation organized and existing under the laws of the State of Pennsylvania and having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

**Jurisdiction and Venue**

29. This Court has subject matter jurisdiction over the counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a) and 1367, based on an actual controversy between Lupin and Counterclaim Defendant OMJPI arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

30. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391, 1400(b), and by Counterclaim-Defendants’ choice of forum.

**First Counterclaim**  
**(Declaration of Invalidity of the '815 Patent)**

31. Lupin incorporates by reference the allegations set forth in paragraphs 25 through 30 of the Counterclaims as if fully set forth herein.

32. There is an actual case or controversy as to the validity of claims 1 through 4 of the '815 patent.

33. The '815 patent, including claims 1 through 4 thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and 112.

**Prayer for Relief**

WHEREFORE, Lupin prays that this Court enters judgment against Plaintiffs:

- A. Declaring that the claims of the '815 patent are invalid;
- B. A judgment and order declaring that the manufacture, use, sale, offer for sale, or importation of Lupin's norgestimate and ethinyl estradiol tablets (0.180 mg/0.025 mg, 0.215 mg/0.025 mg, 0.250 mg/0.025 mg) that are the subject of ANDA No. 200541, would not, if marketed, infringe any valid and/or enforceable claim of the '815 patent.
- C. Awarding Lupin its costs and expenses incurred in this action; and

D. Awarding Lupin such other and further relief as the Court may deem proper.

Respectfully submitted,

Dated: February 17, 2010

By: /s/ Karen A. Confoy  
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**CERTIFICATION PURSUANT TO L.CIV.R. 11.2**

I hereby certify that the matter here in controversy is not the subject of any other court, arbitration or administrative proceeding.

This action alleges infringement of the same patent at issue in the consolidated matters *Ortho-McNeil-Janssen Pharmaceuticals, Inc., et al. v. Watson Laboratories* and *Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. Sandoz Inc.*, Docket No. 08-5103 (SRC), and of the patent issue in *Ortho-McNeil Pharmaceutical, Inc., et al. v. Barr Laboratories, Inc.*, No. 03-4678 (SRC).

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Dated: February 17, 2010