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

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|---|---|
| **ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA, INC.,**<br><br>**Defendants.** | **Civil Action No.: 3:07-cv-06020 (MLC)(JJH)** |

**PLAINTIFFS' REPLY TO COUNTERCLAIM OF DEFENDANTS, AUROBINDO PHARMA LIMITED AND AUROBINDO PHARMA USA, INC.**

Plaintiffs, AstraZeneca Pharmaceuticals LP ("AstraZeneca Pharma"), AstraZeneca UK Limited ("AstraZeneca UK"), IPR Pharmaceuticals, Inc. ("IPR"), and Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") (collectively, "Plaintiffs"), through their undersigned counsel, reply to separate defenses and a counterclaim of Defendants, Aurobindo Pharma Limited

("Aurobindo India") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (collectively, "Defendants") as follows.

## ANSWER TO SEPARATE DEFENSES

1. The Court lacks subject-matter jurisdiction over Count II of the Complaint (D.I. 1 at p. 7 ¶¶26-31).

**Answer**: Plaintiffs deny the allegations contained in paragraph 1 of the Separate Defenses.

2. One or more of the claims of the '314 patent is invalid for failing to satisfy one or more of the conditions of patentability set forth in Title 35, United States Code, including §§ 102, 103, 112, and 251 thereof.

**Answer**: Plaintiffs deny the allegations contained in paragraph 2 of the Separate Defenses.

3. Aurobindo India reserves all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the Patent Laws of the United States, and any other defenses at law or in equity, that may now exist or in the future be available based on discovery or further factual investigation in this case.

**Answer**: Plaintiffs deny that Aurobindo India and Aurobindo USA are entitled to any relief from affirmative defenses under Rule 8(c), the Patent Laws of the United States, or any other defenses at law or in equity.

## ANSWER TO THE COUNTERCLAIM

### PARTIES

1. Aurobindo India is a corporation operating and existing under the laws of India with its principal place of business at Plot # 2, Maitri Vihar, Ameerpet, Hyderabad - 500 038, Andhra Pradesh, India.

**Answer:** Plaintiffs admit, on information and belief, the allegations contained in paragraph 1 of the Counterclaim.

2. AstraZeneca Pharma purports to be a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803 USA.

**Answer:** Plaintiffs admit the allegations contained in paragraph 2 of the Counterclaim.

3. AstraZeneca UK purports to be a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London WlK lLN, England.

**Answer:** Plaintiffs admit the allegations contained in paragraph 3 of the Counterclaim.

4. IPR purports to be a corporation operating and existing under the laws of Puerto Rico with its principal place of business at Carr 188 Lote 17, San Isidro Industrial Park, Canovanas, Puerto Rico 00729.

**Answer:** Plaintiffs admit the allegations contained in paragraph 4 of the Counterclaim.

5. Shionogi purports to be a corporation operating and existing under the laws of Japan with its principal place of business at 1-8, Doshomachi 3-chome, Chuo-ku, Osaka 541-0045 Japan.

**Answer:** Plaintiffs admit the allegations contained in paragraph 5 of the Counterclaim.

**JURISDICTION AND VENUE**

6. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28, U.S.C. §§ 2201 and 2202.

**Answer:** Plaintiffs admit that Aurobindo India and Aurobindo USA's counterclaim for a declaration of patent invalidity arises under the patent laws of the United States, 35 U.S.C. §1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202, but deny that the counterclaim is valid or sustainable.

7. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction of this forum by suing Defendants in this District, and/or because Plaintiffs conduct substantial business in this District.

**Answer:** Plaintiffs admit that this Court has personal jurisdiction over Plaintiffs for this action. Plaintiffs deny all other allegations in paragraph 7 not specifically admitted.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 139l(b) and l400(b).

**Answer:** Plaintiffs admit that venue is proper in this jurisdictional district for the purpose of this action.

**PATENT-IN-SUIT**

9. On or about August 7, 2001, the U.S. Patent and Trademark Office ("PTO") reissued U.S. Reissue Patent No. RE 37,314 E ("the '314 patent"), entitled "Pyrimidine Derivatives," to Kentaro Hirai, Teruyuki Ishiba, Haruo Koike and Masamichi Watanabe.

**Answer:** Plaintiffs admit the allegations contained in paragraph 9 of the Counterclaim except that "RE 37,314 E" is "RE 37,314."

10. Plaintiffs purport and claim to own, and to have the right to enforce the '314 patent.

**Answer:** Plaintiffs admit the allegations contained in paragraph 10 of the Counterclaim.

11. On or about December 18, 2007, Plaintiffs sued Defendants in this District alleging infringement of the '314 patent under 35 U.S.C. § 271 (e)(2)(A).

**Answer:** Plaintiffs admit the allegations contained in paragraph 11 of the Counterclaim.

**COUNT I**

12. Aurobindo India re-asserts and re-alleges paragraphs 1-11 of this Counterclaim as if fully set forth herein.

**Answer:** Plaintiffs reassert and incorporate by reference their replies to paragraphs 1-11 of the Counterclaim, set forth above.

13. There is an actual, substantial, and continuing justiciable case or controversy between Aurobindo India and Plaintiffs regarding the invalidity of the '314 patent, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. A declaration of rights between the parties is both appropriate and necessary to establish that the '314 patent is invalid and therefore cannot be infringed by Aurobindo India.

**Answer:** Plaintiffs admit that there is an actual and justiciable case or controversy concerning the '314 patent between Plaintiffs and Defendants sufficient to confer declaratory judgment jurisdiction. Plaintiffs deny the remaining allegations contained in paragraph 13 of the Counterclaim.

14. The claims of the '314 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code, including §§ 102, 103, 112, and 251 thereof.

**Answer:** Plaintiffs deny the allegations contained in paragraph 14 of the Counterclaim.

15. Aurobindo India is entitled to a judicial declaration that the claims of the '314 patent are invalid.

**Answer**: Plaintiffs deny the allegations contained in paragraph 15 of the Counterclaim.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment against Aurobindo India and Aurobindo USA as follows:

(a) dismissing Aurobindo India and Aurobindo USA's counterclaim with prejudice;

(b) finding that this is an exceptional case and granting Plaintiffs' reasonable attorney fees pursuant to 35 U.S.C. §285; and

(c) awarding Plaintiffs any further and additional relief as this Court deems just and proper.

Respectfully submitted,

Dated: March 6, 2008

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**CERFIFICIATE OF SERVICE**

The undersigned hereby certifies that true copies of Plaintiffs' Reply to Counterclaim of Defendants, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., were caused to be served on March 6, 2008, upon the following via ECF and/or Overnight Mail:

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