IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD., Defendant.	Civil Action No.: 07-806-JJF-LPS

PLAINTIFFS' REPLY TO DEFENSES AND COUNTERCLAIMS
OF SUN PHARMACEUTICAL INDUSTRIES LTD.

Plaintiffs, AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (jointly "Plaintiffs"), through their undersigned counsel, reply to the defenses and counterclaims of Defendant Sun Pharmaceutical Industries Ltd. ("Sun") as follows:

ANSWER TO AFFIRMATIVE DEFENSES

First Affirmative Defense

35. The manufacture, use, sale, offer for sale, or importation of the rosuvastatin calcium tablets that are the subject of ANDA 79-169 will not infringe, directly or indirectly, any valid and enforceable claim of the '314 patent.

Answer: Plaintiffs deny the allegations in Paragraph 35.

Second Affirmative Defense

36. The claims of the '314 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256, and 287.

Answer: Plaintiffs deny the allegations in Paragraph 36.

Third Affirmative Defense

37. Count II of the Complaint fails to state a claim upon which relief can be granted.

Answer: Plaintiffs deny the allegations in Paragraph 37.

Fourth Affirmative Defense

38. The Court lacks subject matter jurisdiction over Count II of the Complaint.

Answer: Plaintiffs deny the allegations in Paragraph 38.

Fifth Affirmative Defense

39. Any additional defenses or counterclaims that discovery may reveal.

Answer: Plaintiffs deny the allegations in Paragraph 39.

ANSWER TO COUNTERCLAIMS

PARTIES

40. Sun is a corporation organized and existing under the laws of India with a principal place of business of at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai 400059, Maharashtra, India.

Answer: Plaintiffs admit, on information and belief, the allegations in Paragraph 40.

41. On information and belief, AstraZeneca Pharmaceuticals LP is a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

Answer: Plaintiffs admit the allegations in Paragraph 41.

42. On information and belief, AstraZeneca UK Limited is a corporation operating and existing under the laws of the United Kingdom with its principal place of business at 15 Stanhope Gate, London W1K lLN, England.

Answer: Plaintiffs admit the allegations in Paragraph 42.

43. On information and belief, IPR Pharmaceuticals, Inc. ("IRP") is 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 in Paragraph 43.

44. On information and belief, Shionogi Seiyaku Kabushiki Kaisha ("Shionogi") is 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 in Paragraph 44.

JURISDICTION AND VENUE

45. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Answer: Plaintiffs admit that Sun's counterclaims purport to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but deny that the counterclaims are valid or sustainable.

46. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

Answer: Plaintiffs admit that this Court has jurisdiction over the counterclaims arising under 28 U.S.C. §§ 1331 and 1338(a).

47. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b).

Answer: Plaintiffs admit that venue is proper for the purposes of this action only. Plaintiffs deny the remaining allegations in Paragraph 47.

48. There is an actual and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '314 patent.

Answer: Plaintiffs admit the allegations in Paragraph 48. Plaintiffs deny the remaining allegations in Paragraph 48.

BACKGROUND

49. On information and belief, IPR is the holder of the approved NDA No. 021366 for rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms.

Answer: Plaintiffs admit the allegations in Paragraph 49.

50. NDA holders are required to disclose to FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. FDA lists these patents in the FDA publication entitled "Approved Drug Products with Therapeutic

Equivalence Evaluations" (the "Orange Book"). On information and belief, IPR caused the '314 patent to be listed in the Orange Book as a patent that claims the drug or that claims a method of using such drug for which IRP submitted NDA No. 021366. On information and belief, Shionogi is the record owner of the '314 patent, and AstraZeneca Pharmaceuticals, LP is the US Agent for IRP.

Answer: Paragraph 50 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that IPR applied for NDA No. 021366, that AstraZeneca Pharmaceuticals, LP is the U.S. agent for IPR for the submission, that Shionogi is the assignee of the '314 patent, and that the '314 patent is listed in the Orange Book. Plaintiffs deny the remaining allegations in Paragraph 50.

51. Sun submitted its ANDA No. 79-169 to obtain FDA approval to engage in the commercial manufacture, use, and sale of rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths prior to the expiration of the '314 patent. ANDA 79-169 contained a Paragraph IV certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '314 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the product described in ANDA No. 79-169.

Answer: Plaintiffs admit, on information and belief, the allegations of Paragraph 51.

52. On December 11, 2007, AstraZeneca filed this instant suit alleging infringement of the '314 patent.

Answer: Plaintiffs admit the allegations in Paragraph 52.

COUNTERCLAIM I

DECLARATORY JUDGMENT OF INVALIDITY OF THE '314 PATENT

53. Sun incorporates by reference the allegations in Paragraphs 40-52 of its counterclaims.

Answer: Plaintiffs incorporate by reference the responses to Sun's allegations in Paragraphs 40-52.

54. On information and belief, the claims of the '314 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256, and 287.

Answer: Plaintiffs deny the allegations of Paragraph 54.

55. There is an actual and justiciable controversy between the parties concerning whether the '314 patent is valid.

Answer: Plaintiffs admit the allegations in Paragraph 55.

56. Sun is entitled to a judicial declaration that the '314 patent is invalid.

Answer: Plaintiffs deny the allegation of Paragraph 56.

COUNTERCLAIM II

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '314 PATENT

57. Sun incorporates by reference the allegations in Paragraphs 40-56 of its counterclaims.

Answer: Plaintiffs incorporate by reference the responses to Sun's allegations in Paragraphs 40-56.

58. The manufacture, use, offering for sale or importation of the rosuvastatin calcium tablets that are the subject of ANDA 79-169 will not infringe, directly or indirectly, any valid and enforceable claim of the '314 patent.

Answer: Plaintiffs deny the allegations of Paragraph 58.

59. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale or importation of the rosuvastatin calcium tablets that are the subject of ANDA 79-169 will infringe the '314 patent.

Answer: Plaintiffs admit the allegations in Paragraph 59.

60. Sun is entitled to a judicial declaration that it has not infringed and does not infringe - directly, by inducement or by contribution - any valid claim of the '314 patent.

Answer: Plaintiffs deny the allegations of Paragraph 60.

* * *

Plaintiffs deny all remaining allegations not specifically admitted herein and deny that Sun is entitled to any relief requested or to any relief at all.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request this Court to enter judgment against Sun as follows:

(a) dismissing Sun's counterclaims with prejudice;

(b) finding that this is an exceptional case and granting AstraZeneca's 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.

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CERTIFICATE OF SERVICE

I hereby certify on this 21st day of March, 2008 I electronically filed the foregoing PLAINTIFFS' REPLY TO DEFENSES AND COUNTERCLAIMS OF SUN PHARMACEUTICAL INDUSTRIES LTD. with the Clerk of Court using CM/ECF which will send notification of such filing to counsel of record.

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The undersigned counsel further certifies that, on March 21, 2008, copies of the foregoing document were also served upon the following individuals in the manner indicated:

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