IN THE UNITED STATES DISTRICT COURT
FOR 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

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF DEFENDANT SUN PHARMACEUTICAL INDUSTRIES LTD.

Defendant Sun Pharmaceutical Industries Ltd. ("Sun"), by and through its undersigned attorneys, submits the following Answer to the Complaint of Plaintiffs Astrazeneca Pharmaceuticals LP, Astrazeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively, "Plaintiffs") as follows:

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. §§ 271(e) and (a). This action relates to an Abbreviated New Drug Application ("ANDA") filed by and/or for the benefit of Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries Inc., and Caraco Pharmaceutical Laboratories Ltd ("the Sun ANDA") with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' highly successful Crestor® pharmaceutical products that are sold in the United States.

RESPONSE TO PARAGRAPH 1:

Paragraph 1 contains conclusions of law for which no response is required. To the

extent a response is required, Sun admits that this action purports to be one for patent infringement and relates to an ANDA filed by Sun with the FDA. Sun denies the remaining allegations in Paragraph 1 of the Complaint.

2. Plaintiff AstraZeneca Pharmaceuticals LP ("AstraZeneca") is a corporation operating and existing under the laws of Delaware with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803 USA.

RESPONSE TO PARAGRAPH 2:

Sun lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2 and thus denies same.

3. Plaintiff 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 W 1 K 1 LN, England.

RESPONSE TO PARAGRAPH 3:

Sun lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3 and thus denies same.

4. Plaintiff IPR Pharmaceuticals, Inc. ("IPR") 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.

RESPONSE TO PARAGRAPH 4:

Sun lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 4 and thus denies same.

5. Plaintiff Shionogi Seiyaku Kabushiki Kaisha 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.

RESPONSE TO PARAGRAPH 5:

Sun lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 5 and thus denies same.

6. On information and belief, Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is a corporation operating and existing under the laws of India with its principal place of business at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai 400059, Maharashtra, India.

RESPONSE TO PARAGRAPH 6:

Admitted.

7. On information and belief, Defendant Sun Pharmaceutical Industries Inc. ("Sun USA") is a wholly owned subsidiary of Sun Ltd. and is a corporation operating and existing under the laws of Delaware with its principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512 USA.

RESPONSE TO PARAGRAPH 7:

Sun admits that Sun Pharmaceutical Industries Inc. ("Sun USA") is a wholly owned subsidiary of Sun and has its principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512 USA. Sun denies that Sun USA is a defendant because Plaintiffs filed a Notice of Voluntary Dismissal on January 2, 2007, that dismissed Sun USA from this lawsuit.

8. On information and belief, Caraco Pharmaceutical Laboratories's Ltd. ("Caraco") is a corporation operating and existing under the laws of Michigan with its principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202 USA. On information and belief, a majority of Caraco's common stock is owned by Sun Ltd.

RESPONSE TO PARAGRAPH 8:

Sun admits that Caraco Pharmaceutical Laboratories Ltd. ("Caraco") is a corporation operating and existing under the laws of Michigan with its principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202 USA. Sun denies that Caraco is a defendant because Plaintiffs filed a Notice of Voluntary Dismissal on January 2, 2007, that dismissed Caraco from this lawsuit.

9. IPR is the holder of approved New Drug Application ("NDA") No. 021366 for Crestor® Tablets, in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms, containing rosuvastatin calcium. AstraZeneca is IPR's authorized agent for matters related to NDA No. 021366.

RESPONSE TO PARAGRAPH 9:

Sun admits that IPR is identified by the FDA as the holder of approved NDA No. 021366 for rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage forms. Sun is lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 9 and thus denies same.

10. CRESTOR® (rosuvastatin calcium) is a prescription drug belonging to a group of medicines (called statins) that are used to treat high cholesterol. Crestor® is one of the most effective lipid-lowering statins available. Over 11 million patients have been prescribed Crestor®, and over 110 million prescriptions have been written worldwide for Crestor®.

RESPONSE TO PARAGRAPH 10:

Sun admits that a commercial formulation of rosuvastatin calcium approved by the FDA for the treatment of high cholesterol is sold under the trademark CRESTOR®. Sun lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 10 and thus denies same.

11. Plaintiffs, among other things, manufacture, market, promote, educate the public and physicians about, and conduct research and development on existing and new indications for Crestor® Tablets. Plaintiffs financially benefit from sales of Crestor® Tablets in the United States.

RESPONSE TO PARAGRAPH 11:

Sun lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 11 and thus denies same.

12. On information and belief, Sun Ltd., Sun USA, and/or Caraco filed with the FDA, in Rockville, Maryland, ANDA No. 79-169 under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, which are generic versions of Plaintiffs' Crestor® Tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths, respectively.

RESPONSE TO PARAGRAPH 12:

Sun admits that it filed with the FDA ANDA No. 79-169 for rosuvastatin calcium tablets bioequivalent to the commercial formulation of rosuvastatin calcium marketed under the trademark CRESTOR®. Sun further admits that it filed the ANDA to obtain FDA approval to engage in the commercial manufacture and sale of its proposed rosuvastatin calcium tablets. Sun denies the remaining allegations in Paragraph 12 of the Complaint.

13. By letter dated November 16, 2007, Sun Ltd. notified Plaintiffs that it had filed an ANDA seeking FDA approval to market rosuvastatin calcium tablets in 5 mg, 10 mg, 20 mg, and 40 mg dosage strengths (hereinafter referred to as "the Sun Rosuvastatin Calcium Tablets"), and that it was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

RESPONSE TO PARAGRAPH 13:

Sun admits that it sent Plaintiffs a letter dated November 16, 2007, providing information pursuant to 21 U.S.C. § 355(J)(2)(B)(ii) and 21 C.R.R. § 314.95(c) relating to ANDA No. 79-169 for rosuvastatin calcium tablets bioequivalent to the commercial

formulation of rosuvastatin calcium marketed under the brand name CRESTOR®. Sun denies the remaining allegations in Paragraph 13.

14. On information and belief, Sun Ltd. is in the business of developing and manufacturing generic pharmaceutical products. On information and belief, Sun Ltd. claims to have a successful generic presence in the United States based on its subsidiaries, Caraco and Sun USA.

RESPONSE TO PARAGRAPH 14:

Sun admits that it is in the business of developing and manufacturing generic pharmaceutical products. Sun also admits it has sold and delivered pharmaceutical products to Caraco pursuant to agreements with Caraco. Sun denies the remaining allegations in Paragraph 14.

15. On information and belief, Sun Ltd. sells and delivers its pharmaceutical products to Sun USA in New Jersey and Caraco in Michigan. On information and belief Sun USA and Caraco are the agents, affiliates, representatives, and/or alter egos of, and/or act in concert with, Sun Ltd. for the purposes of marketing, distributing, and selling generic pharmaceutical products within the United States, including the State of Delaware.

RESPONSE TO PARAGRAPH 15:

Sun admits it has sold and delivered pharmaceutical products to Caraco pursuant to agreements with Caraco. Sun denies the remaining allegations in Paragraph 15.

16. On information and belief, Sun USA and Caraco, as the authorized agents of Sun Ltd. and/or in their own capacity, participated in the preparation and filing with the FDA of the Sun ANDA for approval to market generic rosuvastatin calcium in the United States.

RESPONSE TO PARAGRAPH 16:

Denied.

17. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

RESPONSE TO PARAGRAPH 17:

Paragraph 17 contains conclusions of law for which no response is required.

18. On information and belief, Sun Ltd. develops and manufactures generic drugs and, directly or indirectly through Sun USA and/or Caraco, markets, distributes, and sells its generic drugs throughout the United States, including the State of Delaware.

RESPONSE TO PARAGRAPH 18:

Sun admits that it develops and manufactures generic drugs. Sun denies the remaining allegations in Paragraph 18.

19. Personal jurisdiction over Sun Ltd. is proper because it purposefully avails itself of the privilege of selling its generic products in the state of Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware. Among other things, upon information and belief, Sun Ltd., directly or through its subsidiaries Sun USA and/or Caraco,

places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware.

RESPONSE TO PARAGRAPH 19:

Paragraph 19 contains conclusions of law for which no response is required. Sun denies the remaining allegations in Paragraph 19.

20. Personal jurisdiction over Sun USA is proper because it purposefully avails itself of the privilege of selling its generic products in the state of Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware. Among other things, upon information and belief, Sun USA directly places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware.

RESPONSE TO PARAGRAPH 20:

Paragraph 20 contains conclusions of law for which no response is required.

21. Personal jurisdiction over Caraco is proper because it purposefully avails itself of the privilege of selling its generic products in the state of Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware. Among other things, upon information and belief, Caraco directly places goods into the stream of commerce for distribution throughout the United States, including the State of Delaware.

RESPONSE TO PARAGRAPH 21:

Paragraph 21 contains conclusions of law for which no response is required.

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

RESPONSE TO PARAGRAPH 22:

Paragraph 22 contains conclusions of law for which no response is required.

Count I

Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(e)(2)

23. Plaintiffs incorporate by reference paragraphs 1-22 of this Complaint as if fully set forth herein.

RESPONSE TO PARAGRAPH 23:

Sun incorporates by reference its answers above to Paragraphs 1-22 of the Complaint.

24. United States Patent No. RE37,314 ("the '314 patent"), entitled "Pyrimidine Derivatives," was duly and legally reissued by the United States Patent and Trademark Office on August 7, 2001. Plaintiffs hold all substantial rights in the '314 patent and have the right to sue for infringement thereof. A true and correct copy of the '314 patent is attached as Exhibit A.

RESPONSE TO PARAGRAPH 24:

Paragraph 24 contains conclusions of law for which no response is required. To the extent a response is required, Sun admits that the '314 patent is entitled "Pyrimidine Derivatives" and states on its face that it reissued on August 7, 2001. Sun admits that a copy of the '314 patent was attached as Exhibit A to the Complaint. Sun denies the remaining allegations in Paragraph 24 of the Complaint.

25. On information and belief, Sun Ltd., Sun USA, and Caraco filed ANDA No. 79-169 in order to obtain approval to market the Sun Rosuvastatin Calcium Tablets in the United States before the expiration of the '314 patent. On information and belief, Sun Ltd., Sun USA, and Caraco also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '314 patent are invalid and that the '314 patent is unenforceable.

RESPONSE TO PARAGRAPH 25:

Sun admits that it filed ANDA 79-169, that the ANDA is directed to rosuvastatin calcium and its use, and that the ANDA included a certification under 21 U.S.C. § 355(J)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4). Sun denies the remaining allegations in Paragraph 25 of the Complaint.

26. On information and belief, Sun Ltd., Sun USA, and Caraco do not assert that Sun Rosuvastatin Calcium Tablets are not covered by one or more claims of the '314 patent.

RESPONSE TO PARAGRAPH 26:

Denied.

27. Under 35 U.S.C. § 271(e)(2)(A), the submission by Sun Ltd., Sun USA, and/or Caraco to the FDA of ANDA No. 79-169 to obtain approval for the commercial manufacture, use, or sale of the Sun Rosuvastatin Calcium Tablets before the expiration date of the '314 patent constitutes infringement of one or more claims of the '314 patent, either literally or under the doctrine of equivalents.

RESPONSE TO PARAGRAPH 27:

Denied.

28. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

RESPONSE TO PARAGRAPH 28:

Denied.

Count II

Declaratory Judgment of Infringement of United States Patent No. RE37,314 Under 35 U.S.C. § 271(a)

29. Plaintiffs incorporate by reference paragraphs 1-28 of this Complaint as if fully set forth herein.

RESPONSE TO PARAGRAPH 29:

Sun has moved to dismiss Count II under Rule 12(b)(1) of the Federal Rules of Civil Procedure ("Rules"). Any answer to this allegation will be filed under Rule 12(a)(4).

30. Upon information and belief, Sun Ltd., Sun USA, and Caraco have made substantial preparations to sell Sun Rosuvastatin Calcium Tablets labeled for the same dosages as the Crestor® products.

RESPONSE TO PARAGRAPH 30:

Sun has moved to dismiss Count II under Rule 12(b)(1). Any answer to this allegation will be filed under Rule 12(a)(4).

31. Upon information and belief, Sun Ltd., Sun USA, and Caraco intend to commence sale of Sun Rosuvastatin Calcium Tablets immediately upon receiving approval from the FDA.

RESPONSE TO PARAGRAPH 31:

Sun has moved to dismiss Count II under Rule 12(b)(1). Any answer to this allegation will be filed under Rule 12(a)(4).

32. The manufacture, importation, sale, and offer for sale of Sun Rosuvastatin Calcium Tablets, once approved by the FDA, will directly infringe, induce and/or contribute to the infringement of one or more claims of the '314 patent under 35 U.S.C. § 271(a).

RESPONSE TO PARAGRAPH 32:

Sun has moved to dismiss Count II under Rule 12(b)(1). Any answer to this allegation will be filed under Rule 12(a)(4).

33. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

RESPONSE TO PARAGRAPH 33:

Sun has moved to dismiss Count II under Rule 12(b)(1). Any answer to this allegation will be filed under Rule 12(a)(4).

34. An actual controversy exists relating to Sun Ltd., Sun USA, and Caraco's threatened infringement of the '314 patent.

RESPONSE TO PARAGRAPH 34:

Sun has moved to dismiss Count II under Rule 12(b)(1). Any answer to this allegation will be filed under Rule 12(a)(4).

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.

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.

Third Affirmative Defense

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

Fourth Affirmative Defense

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

Fifth Affirmative Defense

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

WHEREFORE, Sun requests that the Complaint be dismissed with prejudice and that Sun be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

COUNTERCLAIMS

Sun, for its counterclaims against Plaintiffs, alleges as follows:

The Parties

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

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.

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 1LN, England.

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.

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.

Jurisdiction and Venue

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

46. This Court has jurisdiction over these counterclaims 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).

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

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.

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.

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.

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

COUNT I

(Declaratory Judgment of Invalidity of the '314 Patent)

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

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.

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

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

COUNT II

(Declaratory Judgment of Non-Infringement of the '314 Patent)

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

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.

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.

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.

PRAYER FOR RELIEF

WHEREFORE, Sun requests that:

A. The Complaint be dismissed with prejudice;

B. A judgment be entered that the filing of Sun's ANDA No. 79-169 has not infringed, and does not infringe, any valid and enforceable claim of the '314 patent;

C. A judgment be entered that the manufacture, use, offer to sell, sale and/or importation in the United States of America of Sun's products that are the subject of ANDA No. 79-169 do not, and will not, infringe any valid and enforceable claim of the '314 patent;

D. A judgment be entered that the '314 patent is invalid;

E. Sun be awarded its costs in this action;

F. Sun be awarded its attorneys' fees pursuant to 35 U.S.C. § 285; and

G. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

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Dated: January 31, 2008

/s/ John M. Seaman

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CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF, which will send notification of such filing to all registered participants.

I also certify that on January 31, 2008, I caused to be served true and correct copies of the foregoing on the following as indicated below:

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