IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES LTD., and CARACO PHARMACEUTICAL LABORATORIES LTD., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiff AstraZeneca AB ("AstraZeneca"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendants Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd. and Caraco Pharmaceutical Laboratories Ltd. (collectively, "Sun"). This action relates to Abbreviated New Drug Application ("ANDA") Nos. 206078 and 206081 filed by Sun with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 206078, Sun seeks approval to market 2.5 mg and 5 mg saxagliptin hydrochloride tablets, generic versions of AstraZeneca's ONGLYZA® drug product, prior to expiration of RE44,186 ("the RE'186 patent") and U.S. Patent No. 7,951,400 ("the '400 patent").

3. In ANDA No. 206081, Sun seeks approval to market 5 mg/500mg, 2.5 mg/1000 mg and 5 mg/1000 mg saxagliptin hydrochloride and metformin hydrochloride extended-release tablets, generic versions of AstraZeneca's KOMBIGLYZE™ XR drug product, prior to expiration of the RE'186 patent and U.S. Patent No. 8,628,799 ("the '799 patent").

PARTIES

4. Plaintiff AstraZeneca is a company operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

5. Plaintiff's subsidiary, AstraZeneca Pharmaceuticals LP, is a limited partnership operating and existing under the laws of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

6. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for Type II diabetes. Through its subsidiary, AstraZeneca Pharmaceuticals LP, AstraZeneca markets and sells ONGLYZA® and KOMBIGLYZE™ XR in this judicial district and throughout the United States.

7. Upon information and belief, Sun Pharma Global FZE is a limited liability company incorporated under the provisions of Sharjah's Emiri Decree Number (2) of 1995, having a principal place of business at Office #43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates. Upon information and belief, Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Global Inc., a corporation organized and existing under the laws of the British Virgin Islands, which in turn is a wholly-owned subsidiary of defendant Sun Pharmaceutical Industries Ltd. Upon information and belief, Sun Pharma Global FZE, either on

its own or through its affiliates, is in the business of marketing, distributing and selling pharmaceutical products throughout the United States, including in this district.

8. Upon information and belief, defendant Sun Pharmaceutical Industries Ltd. is a company organized and existing under the laws of India, having a principal place of business at Acme Plaza, Andheri-Kurla Rd., Andheri (E), Mumbai – 400 059, India.

9. Upon information and belief, Caraco Pharmaceutical Laboratories Ltd. is a corporation organized and existing under the laws of Michigan, having a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202. Upon information and belief, Caraco Pharmaceutical Laboratories Ltd. is the surviving entity of a merger between Caraco Pharmaceutical Laboratories Ltd. and Sun Pharmaceutical Industries, Inc. Upon information and belief, Caraco Pharmaceutical Laboratories Ltd. has a branch at 270 Prospect Plains Rd., Carnbury, NJ 08512. Upon information and belief, Caraco Pharmaceutical Laboratories Ltd. is a wholly-owned subsidiary of defendant Sun Pharmaceutical Industries Ltd., and its New Jersey branch is Sun Pharma Global FZE's designated agent for service with respect to ANDA Nos. 206078 and 206081.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

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

12. This Court has jurisdiction over Sun because, *inter alia*, this action arises from actions of Sun directed toward Delaware and because Sun has purposefully availed itself of the

rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Sun regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, Sun derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

13. Sun has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertion of counterclaims.

14. In the alternative, this Court has jurisdiction over Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

15. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Sun.

PATENTS-IN-SUIT

16. On April 30, 2013, the U.S. Patent and Trademark Office duly and legally reissued the RE'186 patent, titled "Cyclopropyl-Fused Pyrrolidine-Based Inhibitors of Dipeptidyl Peptidase IV and Method." The RE'186 patent is a reissue of U.S. Patent No. 6,395,767 ("the '767 patent"), which issued on May 28, 2002. A true and correct copy of the RE'186 patent is attached hereto as **Exhibit A**. The claims of the RE'186 patent are valid and enforceable. AstraZeneca is the owner of the RE'186 patent by assignment and has the right to enforce it.

17. On May 31, 2011, the U.S. Patent and Trademark Office duly and legally issued the '400 patent, entitled "Coated Tablet Formulation and Method." A true and correct copy of the '400 patent is attached hereto as **Exhibit B**. The claims of the '400 patent are valid and enforceable. AstraZeneca is the owner of the '400 patent by assignment and has the right to enforce it.

18. On January 14, 2014, the U.S. Patent and Trademark Office duly and legally issued the '799 patent, entitled "Coated Tablet Formulation and Method." A true and correct copy of the '799 patent is attached hereto as **Exhibit C**. The claims of the '799 patent are valid and enforceable. AstraZeneca is the owner of the '799 patent by assignment and has the right to enforce it.

19. AstraZeneca is the holder of New Drug Application ("NDA") No. 022350, by which the FDA granted approval for the marketing and sale of 2.5 mg and 5 mg strength saxagliptin hydrochloride tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus in multiple clinical settings. AstraZeneca markets saxagliptin hydrochloride tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "ONGLYZA®." The FDA's official publication of approved drugs (the "Orange Book") includes ONGLYZA® together with the RE'186 and '400 patents.

20. AstraZeneca is the holder of New Drug Application ("NDA") No. 200678 by which the FDA granted approval for the marketing and sale of 5 mg/500 mg, 5 mg/1000 mg and 2.5 mg/1000 mg strength saxagliptin hydrochloride and metformin hydrochloride extended release tablets as an adjunct to diet and exercise to improve glycemic control in adults with type

2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate. AstraZeneca markets saxagliptin hydrochloride and metformin hydrochloride tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "KOMBIGLYZE™ XR." The Orange Book includes 5 mg/500 mg strength KOMBIGLYZE™ XR together with the RE'186 and '799 patents. The Orange Book includes 5 mg/1000 mg and 2.5 mg/1000 mg strength KOMBIGLYZE™ XR together with the RE'186 patent.

INFRINGEMENT BY SUN

A. Submission of ANDA No. 206078

21. By letter dated April 24, 2014, Sun purported to notify AstraZeneca that Sun Pharma Global FZE had submitted ANDA No. 206078 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("the Onglyza Notice Letter").

22. Although the face of the Onglyza Notice Letter states that it was sent via FedEx Courier to AstraZeneca, AstraZeneca has not located any documentation evidencing delivery via FedEx. On information and belief, service of the Onglyza Notice Letter was ineffective.

23. The Onglyza Notice Letter states that Sun seeks approval from the FDA to engage in the commercial manufacture, use, and sale of generic saxagliptin hydrochloride tablets before the expiration of the RE'186 and '400 patents. Upon information and belief, Sun intends to engage in the commercial manufacture, use, and sale of its generic saxagliptin hydrochloride tablets promptly upon receiving FDA approval to do so.

24. By filing ANDA No. 206078, Sun has necessarily represented to the FDA that its generic saxagliptin hydrochloride tablets have the same active ingredient as ONGLYZA®, have

the same method of administration, dosage form, and strengths as ONGLYZA®, and are bioequivalent to ONGLYZA®.

25. ANDA No. 206078 contains a "Paragraph IV certification" asserting that the RE'186 and '400 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Sun's generic saxagliptin hydrochloride tablets.

26. This Complaint is being filed before the expiration of the forty-five days from the date of the Onglyza Notice Letter.

B. Submission of ANDA No. 206081

27. By letter dated April 24, 2014, Sun purported to notify AstraZeneca that Sun had submitted ANDA No. 206081 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("the Kombiglyze Notice Letter").

28. Although the face of the Kombiglyze Notice Letter states that it was sent via FedEx Courier to AstraZeneca, AstraZeneca has not located any documentation evidencing delivery via FedEx. On information and belief, service of the Kombiglyze Notice Letter was ineffective.

29. The Kombiglyze Notice Letter states that Sun seeks approval from the FDA to engage in the commercial manufacture, use, and sale of generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets before the expiration of the RE'186 and '799 patents. Upon information and belief, Sun intends to engage in the commercial manufacture, use, and sale of its generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets promptly upon receiving FDA approval to do so.

30. By filing ANDA No. 206081, Sun has necessarily represented to the FDA that its generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets have the same active ingredient as KOMBIGLYZE™ XR, have the same method of administration, dosage form, and strengths as KOMBIGLYZE™ XR, and are bioequivalent to KOMBIGLYZE™ XR.

31. ANDA No. 206081 contains a "Paragraph IV certification" asserting that the RE'186 and '799 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Sun's generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets.

32. This Complaint is being filed before the expiration of the forty-five days from the date of the Kombiglyze Notice Letter.

COUNT I (INFRINGEMENT OF THE RE'186 PATENT) (ANDA NO. 206078)

33. Each of the preceding paragraphs 1 to 32 is incorporated as if fully set forth herein.

34. Sun's submission of ANDA No. 206078 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic saxagliptin hydrochloride tablets prior to the expiration of the RE'186 patent constituted a technical act of infringement. Upon information and belief, the product described in ANDA No. 206078 would infringe one or more of the claims of the RE'186 patent under 35 U.S.C. § 271(e)(2)(A).

35. Upon information and belief, upon FDA approval of Sun's ANDA No. 206078, Sun will further infringe at least one claim of the RE'186 patent by making, using, offering to sell, and selling its generic saxagliptin hydrochloride tablets in the United States and/or

importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

36. If Sun's marketing and sale of generic saxagliptin hydrochloride tablets prior to expiration of the RE'186 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE '400 PATENT) (ANDA NO. 206078)

37. Each of the preceding paragraphs 1 to 36 is incorporated as if fully set forth herein.

38. Sun's submission of ANDA No. 206078 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic saxagliptin hydrochloride tablets prior to the expiration of the '400 patent constituted a technical act of infringement. Upon information and belief, the product described in ANDA No. 206078 would infringe one or more of the claims of the '400 patent under 35 U.S.C. § 271(e)(2)(A).

39. Upon information and belief, upon FDA approval of Sun's ANDA No. 206078, Sun will further infringe at least one claim of the '400 patent by making, using, offering to sell, and selling its generic saxagliptin hydrochloride tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

40. If Sun's marketing and sale of generic saxagliptin hydrochloride tablets prior to expiration of the '400 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III (INFRINGEMENT OF THE RE'186 PATENT) (ANDA NO. 206081)

41. Each of the preceding paragraphs 1 to 40 is incorporated as if fully set forth herein.

42. Sun's submission of ANDA No. 206081 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets prior to the expiration of the RE'186 patent constituted a technical act of infringement. Upon information and belief, the product described in ANDA No. 206081 would infringe one or more of the claims of the RE'186 patent under 35 U.S.C. § 271(e)(2)(A).

43. Upon information and belief, upon FDA approval of Sun's ANDA No. 206081, Sun will further infringe at least one claim of the RE'186 patent by making, using, offering to sell, and selling its generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

44. If Sun's marketing and sale of generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets prior to expiration of the RE'186 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV (INFRINGEMENT OF THE '799 PATENT) (ANDA NO. 206081)

45. Each of the preceding paragraphs 1 to 44 is incorporated as if fully set forth herein.

46. Sun's submission of ANDA No. 206081 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets prior to the expiration of the '799 patent constituted a technical act of infringement. Upon information and belief, at least one dosage strength of the product described in ANDA No. 206081 would infringe one or more of the claims of the '799 patent under 35 U.S.C. § 271(e)(2)(A).

47. Upon information and belief, upon FDA approval of Sun's ANDA No. 206081, Sun will further infringe at least one claim of the '799 patent by making, using, offering to sell, and selling at least one dosage strength of its generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

48. If Sun's marketing and sale of at least one infringing dosage strength of its generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets prior to expiration of the '799 patent and all other relevant exclusivities is not enjoined, AstraZeneca will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AstraZeneca prays that this Court grant the following relief:

1. A judgment that the claims of the RE'186 and '400 patents are not invalid, not unenforceable, and are infringed by Sun's submission of ANDA No. 206078, and that Sun's making, using, offering to sell, or selling in the United States, or importing into the United States Sun's generic saxagliptin hydrochloride tablets will infringe the RE'186 and '400 patents.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 206078 shall be a date which is not earlier than the latest expiration date of the RE'186 and '400 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

3. An order permanently enjoining Sun, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Sun's generic saxagliptin hydrochloride tablets until after the latest expiration date of the RE'186 and '400 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

4. Damages or other monetary relief to AstraZeneca if Sun engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Sun's generic saxagliptin hydrochloride tablets prior to the latest expiration date of the RE'186 and '400 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

5. A judgment that the claims of the RE'186 and '799 patents are not invalid, not unenforceable, and are infringed by Sun's submission of ANDA No. 206081, and that Sun's making, using, offering to sell, or selling in the United States, or importing into the United States Sun's generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets will infringe the RE'186 patent and with regard to at least one dosage strength of Sun's generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets, the '799 patents.

6. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 206081 shall be a date which is not earlier than the latest expiration date of the RE'186 and '799 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

7. An order permanently enjoining Sun, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Sun's generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets until after the latest expiration date of the RE'186 and '799 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

8. Damages or other monetary relief to AstraZeneca if Sun engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Sun's generic saxagliptin hydrochloride and metformin hydrochloride extended-release tablets prior to the latest expiration date of the RE'186 and '799 patents, including any extensions and/or additional periods of exclusivity to which AstraZeneca is or becomes entitled.

9. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: June 2, 2014

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