IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, Plaintiff, v. AUROBINDO PHARMA LTD., et al. Defendants.	C.A. No. 14-664-GMS (CONSOLIDATED)

MEMORANDUM

I. INTRODUCTION

In this consolidated patent infringement action, plaintiff AstraZeneca alleges that pharmaceutical products proposed by defendants Aurobindo Pharma Ltd., Aurobindo Pharma U.S.A., Wockhardt Bio AG, Wochardt USA LLC, Amneal Pharmaceuticals LLC, Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, Mylan Pharmaceuticals Inc., Watson Laboratories, Inc., and Actavis Laboratories FL, Inc. (collectively "Aurobindo") infringe the asserted claims of U.S. Reissue Patent No. RE44,186 ("RE'186 patent" or "the patent-in-suit").[1] The court held a three-day bench trial on September 19, 2016 through September 21, 2016. (D.I. 369-371.) Presently before the court are the parties' proposed finding of fact and conclusions of law concerning the validity of the RE'186 patent, specifically whether the asserted claims are invalid as obvious under 35 U.S.C. § 103. (D.I. 373, 374, 375.)

[1] AstraZeneca asserts claims 25 and 26 of the RE'186 patent. Two additional patents were originally at issue: U.S. Patent No.7,951,400 ("'400 patent") and U.S. Patent No. 8,628,799 ("'799 patent"). Following stipulations dismissing all claims concerning the '400 patent and '799 patent, the court dismissed these cases from the consolidated action: Civil Action Nos. 14-cv-665, 14-cv-666, 14-cv-695, 14-cv-698, and 14-cv-845.

Pursuant to Federal Rule of Civil Procedure 52(a), having considered the entire record in this case and the applicable law, the court concludes that the asserted claims of the RE'186 patent are not invalid due to obviousness. These findings of fact and conclusions of law are set forth in further detail below.

II. Findings of Fact[2]

A. The Parties

1. 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.

2. 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.

3. Wockhardt Bio AG. is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Grafenauweg 6, 6300 Zug, Switzerland.

4. Wockhardt USA LLC is a limited liability company, existing under the laws of the State of Delaware and having a principal place of business at 20 Waterview Boulevard, Parsippany, New Jersey 07054.

5. Wockhardt USA LLC is an indirect subsidiary of Wockhardt Bio AG.

6. Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business of Plot #2, Maitri Vihar, Ameerpet, Hyderabad – 500038, Andhra Pradesh, India.

7. Aurobindo Pharma U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810.

8. Aurobindo Pharma U.S.A., Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd.

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[2] Prior to trial, the parties submitted an exhibit of uncontested facts in conjunction with their Pretrial Order. (D.I. 338, Ex. A) The court takes most of its findings of fact from the parties' uncontested facts. Where necessary, the court has overruled objections to the inclusion of these facts. The court has also reordered and renumbered some paragraphs, corrected some spelling and formatting errors, and made minor edits for the purpose of concision and clarity that it does not believe alters the meaning of the paragraphs from the Pretrial Order. Otherwise, any differences between this section and the parties' statement of uncontested facts are unintentional. The court's findings of fact with respect to matters that were the subject of dispute between the parties are included in the Discussion and Conclusions of Law section of this opinion, preceded by the phrase "the court finds" or "the court concludes."

9. Amneal Pharmaceuticals LLC is a limited liability company, existing under the laws of the State of Delaware and having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

10. 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.

11. Sun Pharma Global FZE is a company organized and existing under the laws of the United Arab Emirates, having a principal place of business at Executive Suite #43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates.

12. Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Pharma Global Inc., a corporation organized and existing under the laws of the British Virgin Islands, which in turn is a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd.

13. Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

14. Watson Laboratories, Inc. is a corporation organized and existing under the laws of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

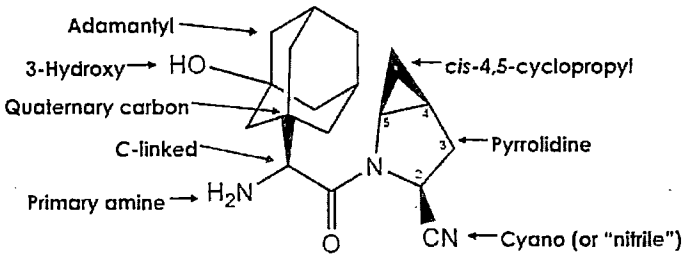
15. Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc. – Florida) is a corporation organized and existing under the laws of Florida, having a principal place of business at 4955 Orange Drive, Davie, Florida 33314.

16. The court has subject matter jurisdiction and personal jurisdiction over all parties.

B. Background

1. These consolidated actions arise out of Defendants' submission of several Abbreviated New Drug Applications ("ANDAs") under § 505(j) of the Federal Food, Drug and Cosmetic Act to the United States Food and Drug Administration ("FDA"), seeking approval to market and sell generic saxagliptin pharmaceutical drug products prior to the expiration of AstraZeneca's RE'186 patent.

2. Saxagliptin is chemical compound that is an FDA-approved DPP4 inhibitor that has been used to treat type 2 diabetes. Saxagliptin has the following chemical structure:



3. Saxagliptin's structure includes a *cis*-4,5-cyclopropyl group fused to a cyanopyrrolidine ring. The resulting *cis*-4,5-cyclopropyl-cyanopyrrolidine moiety represents the P1 group. Saxagliptin also contains a 3-hydroxyadamantyl group that is *C*-linked through a quarternary carbon (a carbon with four non-hydrogen groups attached to it) to the peptide backbone, resulting in primary amine. The *C*-linked 3-hydroxyadamantyl glycine moiety represents the P2 group.

4. 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.

5. AstraZeneca markets 2.5 mg and 5 mg strength saxagliptin hydrochloride tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "Onglyza®."

6. Pursuant to 21 U.S.C. § 355 and attendant FDA regulations, the RE'186 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Onglyza®.

7. The Orange Book includes 2.5 mg and 5 mg strength Onglyza® together with the RE'186 patent.

8. AstraZeneca is the holder of 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.

9. AstraZeneca markets 5 mg/500 mg, 5 mg/1000 mg, and 2.5 mg/1000 mg strength saxagliptin hydrochloride and metformin hydrochloride extended release tablets in the United States, through its Delaware subsidiary AstraZeneca Pharmaceuticals LP, under the trade name "KombiglyzeTM XR."

10. Pursuant to 21 U.S.C. § 355 and attendant FDA regulations, the RE'186 patent is listed in the Orange Book with respect to Kombiglyze TM XR.

11. The Orange Book includes 5 mg/500 mg, 5 mg/1000 mg, and 2.5 mg/1000 mg strength KombiglyzeTM XR together with the RE'186 patent.

C. The Patent-in-Suit

1. U.S. Reissue Patent Number RE44, 186 ("the RE'186 patent"), issued on April 30, 2013, and is entitled "Cyclopropyl-fused pyrrodlidine-based inhibitors of dipeptidyl peptidase IV and method." The RE'186 patent names Jeffrey A. Robl, Richard B. Slusky, David J. Augeri, David R. Magnin, Lawrence G. Hamann, and David A. Betebenner as inventors.

2. AstraZeneca is the assignee of the RE'186 patent.

3. AstraZeneca is the owner by assignment of the RE'186 patent. AstraZeneca has standing to bring suit on the RE'186 patent.

4. U.S. Application No. 13/308,658 ("the '658 Application"), which issued as the RE'186 patent, was filed with the United States Patent and Trademark Office ("PTO") on December 1, 2011.

5. The RE'186 patent is a reissue of U.S. Patent No. 6,395,767 ("the '767 patent"), which originally issued on May 28, 2002.

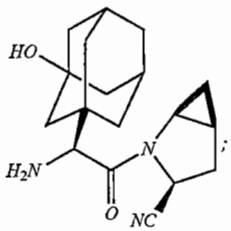
6. The '767 patent was filed on February 16, 2001 and claims priority to provisional application 60/188,155 ("the '155 application) filed on March 10, 2000.

1) The Asserted Claims

7. AstraZeneca has asserted infringement of claims 25 and 26 of the RE'186 patent against each defendant.

i. RE'186 Patent, Claim 25

8. Claim 25 of the RE'186 patent reads: A compound that is



or a pharmaceutically acceptable salt thereof.

ii. RE'186 Patent, Claim 26

9. Claim 26 of the RE'186 patent reads: The compound as defined in claim 25, wherein the pharmaceutically acceptable salt is the hydrochloride salt.

10. Claim 26 is directed to the single compound saxagliptin hydrochloride salt.

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