IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC. and UCB PHARMA GMBH, Plaintiffs, v. SANDOZ INC., *et al.*, Defendants.	C.A. No. 13-1110-GMS **CONSOLIDATED**

MEMORANDUM

I. INTRODUCTION

In this consolidated patent infringement action, Pfizer Inc. and UCB Pharma GmbH (collectively, "the Plaintiffs") allege that Accord Healthcare Inc., USA, Amerigen Pharmaceuticals Ltd., Amerigen Pharmaceuticals, Inc., Amneal Pharmaceuticals, LLC, and Sandoz Inc. (collectively, "the Defendants") infringe the asserted claims of the patents-in-suit. The court held a four-day bench trial in this matter on July 13 through July 16, 2015. Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning the validity of the patents-in-suit, specifically whether the asserted claims are invalid as obvious under 35 U.S.C. § 103. (D.I. 292; D.I. 297.)

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 none asserted claims of the patents-in-suit are invalid due to obviousness. These findings of fact and conclusions of law are set forth in further detail below.

II. FINDINGS OF FACT[1]

A. The Parties

1. Plaintiff Pfizer Inc. ("Pfizer") is a corporation organized and existing under the laws of Delaware and has a place of business at 235 East 42nd Street, New York, New York.

2. Plaintiff UCB Pharma GmbH is an entity organized and existing under the laws of Germany, and has a place of business at Alfred-Nobel-Strasse 10, Monheim, Germany.

3. Defendant Accord Healthcare Inc., USA ("Accord") is a company organized and existing under the laws of North Carolina and has a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina.

4. Defendant Amerigen Pharmaceuticals Ltd. is a corporation organized and existing under the laws of the Cayman Islands and has a registered office at C/O Codan Trust Company (Cayman) Limited, Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman, KY1-1111 Cayman.

5. Defendant Amerigen Pharmaceuticals, Inc. is a company organized and existing under the laws of Delaware and has a principal place of business at 9 Polito Ave., Suite 900, Lyndhurst, New Jersey. Amerigen Pharmaceuticals, Inc. is the U.S. agent for Amerigen Pharmaceuticals Ltd (collectively, "Amerigen").

6. Defendant Amneal Pharmaceuticals, LLC ("Amneal") is a company organized and existing under the laws of Delaware and has a principal place of business at 440 US Highway 22 East, Suite 104, Bridgewater, New Jersey.

7. Defendant Sandoz Inc. ("Sandoz") is a company organized and existing under the laws of Colorado and has a place of business at 100 College Road West, Princeton, New Jersey.

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

B. Background

9. Pfizer holds approved New Drug Application ("NDA") No. 02-2030 for fesoterodine fumarate extended-release tablets, in 4 and 8 mg dosage strengths, which Pfizer sells under the trade name Toviaz®.

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[1] Prior to trial, the parties submitted an exhibit of uncontested facts in conjunction with their Pretrial Order. (D.I. 256, Ex. 1.) The court takes most of its findings of fact from the parties' uncontested facts. The court has also reordered and renumbered some paragraphs 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 Part III this opinion ("Discussion and Conclusions of Law"), preceded by the phrase "the court finds" or "the court concludes."

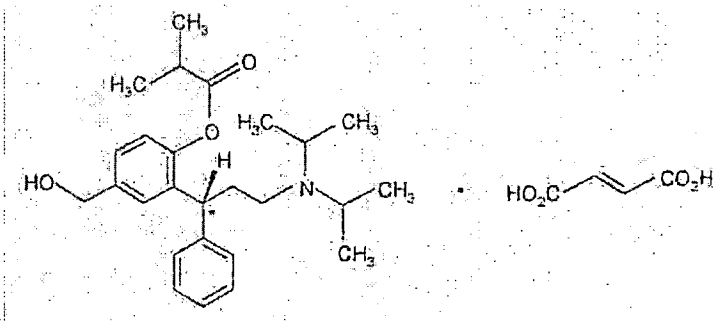
10. Toviaz® is a FDA-approved treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. The FDA first approved the NDA for Toviaz® on October 31, 2008.

11. Pursuant to 21 U.S.C. § 335(b)(1) and attendant FDA regulations, U.S. Patent Nos. 7,384,980 ("the '980 patent"), 7,855,230 ("the '230 patent"), 7,985,772 ("the '772 patent"), 8,338,478 ("the '478 patent"), and 6,858,650 ("the '650 patent") are among the patents listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to Toviaz®.

12. Fesoterodine fumarate is the active pharmaceutical ingredient in Toviaz®.

13. Chemical names for fesoterodine fumarate include:
   a. isobutyric acid 2-((R)-3-diisopropylammonium-1-phenylpropyl)-4-hydroxymethylphenyl ester hydrogen fumarate;
   b. R-(+)-2-(3-diisopropylamino-1-phenyl-propyl)-4-hydroxymethylphenylisobutyrate ester hydrogen fumarate;
   c. R-(+)-2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenylisobutyrate ester hydrogen fumarate;
   d. R-(+)-2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenylisobutyrate ester hydrogen fumarate; and
   e. R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester hydrogen fumarate.

14. The structural formula of fesoterodine fumarate is:



The asterisk (*) indicates the chiral carbon.

C. The Patents-in-Suit

15. Collectively, the '980, '230, '772, and '478 patents may be referred to as the "Compound Patents."

16. The Compound Patents each issued from common parent applications, each of which ultimately claim priority to European Application No. 98108608.5, filed May 12, 1998.

17. The '980 patent issued on June 10, 2008 and is entitled "Derivatives of 3,3-Diphenylpropylamines." The '980 patent names Claus Meese and Bengt Sparf as inventors.

18. The '230 patent issued on December 21, 2010 and is entitled "Derivatives of 3,3-Diphenylpropylamines." The '230 patent names Claus Meese and Bengt Sparf as inventors.

19. The '772 patent issued on July 26, 2011 and is entitled "Derivatives of 3,3-Diphenylpropylamines." The '772 patent names Claus Meese and Bengt Sparf as inventors.

20. The '478 patent issued on December 25, 2012 and is entitled "Derivatives of 3,3-Diphenylpropylamines." The '478 patent names Claus Meese and Bengt Sparf as inventors.

21. The '650 patent issued on February 22, 2005 and is entitled "Stable Salts of Novel Derivatives of 3,3-Diphenylpropylamines." The parties refer to the '650 patent as the "Salt Patent." It claims priority to German Patent Application No. DE 199 55 190 filed November 16, 1999. The '650 patent names Claus Meese as the inventor.

(1) <u>The Asserted Claims</u>

22. The Plaintiffs have asserted infringement of claims 1, 2, 3 and 7 of the '980 patent against each defendant.

23. The Plaintiffs have asserted infringement of claims 3 and 5 of the '230 patent against each defendant.

24. The Plaintiffs have asserted infringement of claim 3 of the '772 patent against each defendant.

25. The Plaintiffs have asserted infringement of claim 3 of the '478 patent against each defendant.

26. The Plaintiffs have asserted infringement of claims 3, 5, 23 and 24 of the '650 patent against each defendant.

i. *'980 Patent, Claim 1*

27. Claim 1 of the '980 patent claims: R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester.

ii. *'980 Patent, Claim 2*

28. Claim 2 of the '980 patent claims: A salt of R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenyl propyl)-4-hydroxymethylphenyl ester with a physiologically acceptable acid.

iii. *'980 Patent, Claim 3*

29. Claim 3 of the '980 patent claims: A pharmaceutical composition comprising an effective amount of R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl

ester, or a salt thereof with a physiologically acceptable acid and a pharmaceutically acceptable carrier.

iv. *'980 Patent, Claim 7*

30. Claim 7 of the '980 patent claims: The method according to claim 6 [*a method according to claim 5 {a method of treating a disease in a mammal that is amenable to treatment by antagonizing muscarinic receptors in the mammal, the method comprising administering to the mammal a pharmaceutical composition comprising an effective amount of R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester or a salt thereof with a physiologically acceptable acid} wherein the disease is urinary incontinence*] wherein the mammal is a human.

v. *'230 Patent, Claim 3*

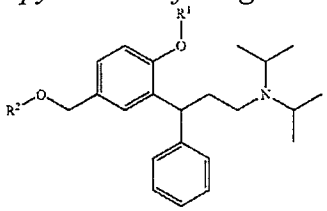
31. Claim 3 of the '230 patent claims: The method according to claim 1 [*a method of treating urinary incontinence in a patient in need thereof, the method comprising administering to the patient an effective amount of a compound selected from the group consisting of: n-butyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester, isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester, propionic acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester, and acetic acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester, including the racemic mixtures and individual enantiomers of said compounds, and a salt of said compounds with a physiologically acceptable acid*], wherein the compound is R-(+) isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester.

vi. *'230 Patent, Claim 5*

32. Claim 5 of the '230 patent claims: The method according to any one of claims 1–4, wherein the compound is administered to the patient in the form of a pharmaceutical composition comprising a pharmaceutically acceptable carrier.

vii. *'772 Patent, Claim 3*

33. Claim 3 of the '772 patent claims: The 3,3-Diphenylpropylamine of claim 1 [*3,3-Diphenylpropylamines of the general formula:*



wherein R1 is hydrogen and R2 is C1-C6 alkylcarbonyl; or R1 is C1-C6 alkylcarbonyl and R2 is hydrogen; their salts with physiologically acceptable acids, their free bases and, when the 3,3-Diphenylpropylamines are in the form of optical isomers, the racemic mixture and the individual enantiomers] wherein R1 is C1-C6 alkylcarbonyl and R2 is hydrogen.

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