UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

Case No. 07-61800-Civ-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants. /

PLAINTIFFS' REPLY TO DEFENDANTS APOTEX INC. AND APOTEX CORP.'S AMENDED COUNTERCLAIMS

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC, for their Reply to the numbered paragraphs of the Counterclaims of Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex"), hereby state as follows:

1. Admitted, upon information and belief.

2. Admitted, upon information and belief.

3. Admitted.

4. Admitted.

5. Admitted that Apotex purports to state declaratory judgment counterclaims that arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355), and the Medicare Prescription Drug, Improvement, and Modernization Act of

2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003), but denied that there is any factual or legal basis for these counterclaims.

6. Admitted that the Court has jurisdiction over the subject matter of the counterclaims related to the '491 patent, but denied that such jurisdiction exists for the counterclaims related to the '940 patent.

7. Plaintiffs do not contest personal jurisdiction in this Court for this Action; to the extent that Paragraph 7 contains any other or further allegations, they are superfluous allegations to which no response is required.

8. While Plaintiffs do not dispute this judicial district is a possible venue for this action, they believe that the District of Delaware is a more convenient venue; therefore on January 8, 2008, Plaintiffs respectfully moved this Court to transfer this action to the District of Delaware where an identical, parallel, first-filed action against Apotex, Civil Action No.07-792 (GMS) (MPT), has been pending since December 6, 2007 in front of the same Judge and Magistrate Judge as two related actions involving the same patent(s), claims and defenses against 13 other defendants, Civil Actions Nos.07-572 (GMS) (MPT) and 07-574 (GMS) (MPT), that have been pending since September 21, 2007.

9. Admitted.

10. Admitted that sanofi-aventis is the assignee of the '491 patent and has a right to enforce the '491 patent.

11. Admitted, except denied that the ‘940 patent issued to anyone named Busto Arisizio.

12. Admitted that sanofi-aventis is an assignee and exclusive licensee of the '940 patent and has a right to enforce the '940 patent.

13. Admitted that the '491 patent and the '940 patent are listed in the Orange Book for Uroxatral®, and that sanofi-aventis U.S. is the holder of New Drug Application No. 21-287.

14. Admitted that plaintiffs have sued other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets for infringement of the '940 patent; otherwise denied.

15. Admitted.

16. Admitted.

17. Admitted.

18. Admitted, except denied that Apotex served its Paragraph IV certification letter, dated October 25, 2007, on or about October 15, 2007.

19. Admitted.

20. Admitted that sanofi-aventis has sued Apotex for infringement of the '491 patent in this District, but denied that Apotex has a reasonable apprehension of being sued by sanofi-aventis for alleged infringement of the '940 patent; to the extent that Paragraph 20 contains any other or further allegations, they are superfluous allegations to which no response is required.

21. The allegations of Paragraph 21 of Apotex's Counterclaims set forth legal conclusions and characterizations to which no response from sanofi-aventis is required. To the extent a response is necessary, sanofi-aventis denies the allegations of Paragraph 21.

22. Admitted, except denied that there is any justiciable controversy as to the validity or infringement of the '940 patent.

23. Plaintiffs restate and incorporate by reference their responses to the allegations contained in Paragraphs 1-22 as though set forth specifically herein.

24. Denied.

25. Denied.

26. Plaintiffs restate and incorporate by reference their responses to the allegations contained in Paragraphs 1-25 as though set forth specifically herein.

27. Denied.

28. Denied.

29. Plaintiffs restate and incorporate by reference their responses to the allegations contained in Paragraphs 1-28 as though set forth specifically herein.

30. The ‘940 patent is not currently in dispute and therefore no response from sanofi-aventis as to the allegations contained within Paragraph 30 is necessary. To the extent a response is necessary, sanofi-aventis denies Paragraph 30.

31. Denied.

32. Plaintiffs restate and incorporate by reference their responses to the allegations contained in Paragraphs 1-31 as though set forth specifically herein.

33. The ‘940 patent is not currently in dispute and therefore no response from sanofi-aventis as to the allegations contained within Paragraph 33 is necessary. To the extent a response is necessary, sanofi-aventis denies Paragraph 33.

34. Denied.

Wherefore, Plaintiffs deny that Apotex Inc. or Apotex Corp. is entitled to any relief, either as prayed for in their Counterclaims or otherwise. Plaintiffs further deny each allegation contained in Apotex Inc. and Apotex Corp.'s Counterclaims that was not specifically admitted, denied, or otherwise responded to in this Reply to Defendant Apotex Inc. and Apotex Corp.'s Counterclaims.

Without prejudice to the denials set forth in its Reply to Defendant Apotex Inc. and Apotex Corp.'s Counterclaims, and without admitting any allegations of the Counterclaims not otherwise admitted, Plaintiffs assert the following defenses to the Counterclaims: (1) Subject matter jurisdiction does not exist for Apotex's counterclaims directed toward the '940 patent; and (2) This second-filed action should be transferred to the more convenient venue of the District of Delaware where an identical, parallel, first-filed action against Apotex has been pending since December 6, 2007 in front of the same Judge and Magistrate Judge as two related actions against 13 other defendants that have been pending since September 21, 2007.

Dated this 17th day of January 2008.
Miami, Florida

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 17, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

Respectfully submitted,

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SERVICE LIST

SANOFI-AVENTIS ET. AL. vs. APOTEX, INC. ET. AL

Case No.: 07-61800-CIV-Moreno/Simonton

United States District Court
Southern District of Florida
(Miami Division)

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VIA CM/ECF