

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BRISTOL-MYERS SQUIBB COMPANY)	
AND PFIZER INC.,)	
)	
Plaintiffs and)	
Counterclaim-Defendants,)	
)	
v.)	C.A. No. 17-cv-399-LPS
)	
APOTEX, INC. AND APOTEX CORP.,)	
)	
Defendants and)	
Counterclaim-Plaintiffs.)	

PLAINTIFFS’ REPLY TO DEFENDANTS’ COUNTERCLAIMS

Plaintiffs and Counterclaim-Defendants Bristol-Myers Squibb Company (“BMS”) and Pfizer Inc. (“Pfizer,” together with BMS, “Plaintiffs”) hereby reply to the Counterclaims of Defendants and Counterclaim-Plaintiffs Apotex, Inc. and Apotex Corp. (collectively, “Apotex”), D.I. 8, as follows. Plaintiffs deny any allegation contained in Apotex’s Answer and Counterclaims not expressly admitted in this Reply.

COUNTERCLAIMS¹

PARTIES

1. Plaintiffs lack knowledge or information sufficient to form a belief about the truth of the allegations in this Paragraph.

2. Plaintiffs lack knowledge or information sufficient to form a belief about the truth of the allegations in this Paragraph.

¹ Plaintiffs have incorporated the headings that appear in Apotex’s Counterclaims. Plaintiffs do not necessarily agree with the characterization of such headings and do not waive any right to object to those characterizations.

3. Admitted.

4. Admitted.

JURISDICTION AND VENUE

5. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Plaintiffs do not contest that the Court has jurisdiction over the subject matter of the Counterclaims.

6. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, BMS does not contest personal jurisdiction in this Court for purposes of the Counterclaims.

7. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Pfizer does not contest personal jurisdiction in this Court for purposes of the Counterclaims.

8. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Plaintiffs do not contest that venue with respect to the Counterclaims is proper in this judicial district.

FACTUAL BACKGROUND

9. Admitted.

10. Admitted.

11. Admitted.

12. Admitted.

13. Admitted.

14. Admitted.

15. Admitted.

16. Plaintiffs admit that they have alleged that the FDA approved NDA No. 202155. Plaintiffs further admit that they have alleged Eliquis[®] is indicated: (1) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (2) for the prophylaxis of deep vein thrombosis (“DVT”), which may lead to pulmonary embolism (“PE”), in patients who have undergone hip or knee replacement surgery; and (3) for the treatment of DVT and PE, and for the reduction in the risk of recurrent DVT and PE following initial therapy. Plaintiffs also admit that they have alleged that they market apixaban tablets under the trade name Eliquis[®].

17. Plaintiffs lack knowledge or information sufficient to form a belief about the truth of the allegations in this Paragraph. Plaintiffs state, however, that Apotex sent Plaintiffs a letter dated March 13, 2017, notifying Plaintiffs that Apotex had submitted ANDA No. 210091 to the FDA, seeking approval to market 2.5 mg and 5 mg tablets of apixaban, generic versions of Plaintiffs’ Eliquis[®] drug product (the “Apotex ANDA product”).

18. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

19. Plaintiffs lack knowledge or information sufficient to form a belief about the truth of the allegations in this Paragraph. Plaintiffs deny, however, that the patents-in-suit are invalid and/or would not be infringed by Apotex’s commercial manufacture, use, offer to sell, sale, or importation of the Apotex ANDA product prior the expiration of the patents-in-suit.

20. This Paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Plaintiffs admit that there is currently a justiciable controversy between the parties regarding the patents-in-suit.

COUNT I
(Declaratory Judgment of Invalidity of the '980 Patent)

21. Plaintiffs hereby incorporate the answers set forth in response to Paragraphs 1 through 20.

22. Plaintiffs admit that Apotex purports to seek a judicial declaration that the claims of the '980 patent are invalid, and that Apotex sent a letter to Plaintiffs dated March 13, 2017 (the "Notice Letter"), asserting that certain claims of the '980 patent are invalid under 35 U.S.C. §§ 101 and/or 112. Otherwise, denied.

COUNT II
(Declaratory Judgment of Non-Infringement of the '980 Patent)

23. Plaintiffs hereby incorporate the answers set forth in response to Paragraphs 1 through 22.

24. Denied.

25. Denied.

COUNT III
(Declaratory Judgment of Invalidity of the '208 Patent)

26. Plaintiffs hereby incorporate the answers set forth in response to Paragraphs 1 through 25.

27. Plaintiffs admit that Apotex purports to seek a judicial declaration that the claims of the '208 patent are invalid, and that Apotex sent the Notice Letter asserting that certain claims of the '208 patent are invalid under 35 U.S.C. §§ 101, 103 and/or 112. Otherwise, denied.

COUNT IV
(Declaratory Judgment of Non-Infringement of the '208 Patent)

28. Plaintiffs hereby incorporate the answers set forth in response to Paragraphs 1 through 27.

29. Denied.

30. Denied.

COUNT V
(Declaratory Judgment of Invalidity of the '945 Patent)

31. Plaintiffs hereby incorporate the answers set forth in response to Paragraphs 1 through 30.

32. Plaintiffs admit that Apotex purports to seek a judicial declaration that the claims of the '945 patent are invalid, and that Apotex sent the Notice Letter asserting that certain claims of the '945 patent are invalid under 35 U.S.C. §§ 103 and/or 112. Otherwise, denied.

COUNT VI
(Declaratory Judgment of Non-Infringement of the '945 Patent)

33. Plaintiffs hereby incorporate the answers set forth in response to Paragraphs 1 through 32.

34. Denied.

35. Denied.

PRAYER FOR RELIEF

Plaintiffs deny that Apotex is entitled to any of the relief sought in its Counterclaims or to any relief whatsoever.

Dated: May 23, 2017

Respectfully submitted,

FARNAN, LLP

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