IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC (f/k/a SMITHKLINEBEECHAM CORPORATION), Plaintiff, v. ANCHEN PHARMACEUTICALS, INC., ANCHEN, INC., and BANNER PHARMACAPS INC., Defendants.	C.A. No. 11-cv-46-SLR

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIM

Defendant Banner Pharmacaps Inc. ("Banner"), for its answer to the Complaint, avers as follows:

1. Paragraph 1 contains legal conclusions to which no answer is required. To the extent that an answer is required, Banner admits that plaintiff purports to bring an action for alleged patent infringement of U.S. Patent No. 5,565,467 ("the '467 patent"), U.S. Patent No. 5,846,976 ("the '976 patent"), and U.S. Patent No. 5,998,427 ("the '427 patent") under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. Banner denies the remaining allegations of paragraph 1.

2. Banner admits that this action relates to an Abbreviated New Drug Application ("ANDA") filed with the U.S. Food and Drug Administration ("FDA"), ANDA No. 200899, filed by Banner for approval to market dutasteride capsules, 0.5 mg, a proposed generic version

of the Avodart.® Banner lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 2.

3. Upon information and belief, Banner admits that GlaxoSmithKline ("GSK") is a Delaware limited liability company having a principal place of business at One Franklin Plaza, Philadelphia, PA 19102. Banner lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 3.

4. Banner admits the allegations of paragraph 4.

5. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 5.

6. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 6.

7. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 7.

8. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 8.

9. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 9.

10. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 10.

11. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 11.

12. Banner admits the allegations of paragraph 12.

13. Paragraph 13 contains legal conclusions to which no answer is required. To the extent that an answer is required, Banner does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. Banner admits that it is incorporated in Delaware, and that in 2008 it filed a counterclaim seeking a declaratory judgment of noninfringement in *Abbott Laboratories v. Banner Pharmacaps Inc.*, C.A. No. 07-cv-754-GMS (D. Del.). Banner denies the remaining allegations of paragraph 13.

14. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 14.

15. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 15.

16. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 16.

17. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 17.

18. Upon information and belief, Banner admits the allegations of paragraph 18.

19. Banner admits the allegations of paragraph 19.

20. Banner admits the allegations of paragraph 20.

21. Upon information and belief, Banner admits the allegations of paragraph 21.

22. Banner admits the allegations of paragraph 22.

23. Banner admits that the '467 patent is entitled "Androstenone Derivative," that it states on its face that it issued on October 15, 1996, and that what purports to be a copy of the '467 patent is attached to the Complaint as Exhibit A. Banner denies that the '467 patent was

duly and legally issued. Banner lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 23.

24. Paragraph 24 contains legal conclusions to which no answer is required. To the extent that an answer is required, Banner avers that the claims of the '467 patent speak for themselves. Banner denies the remaining allegations of paragraph 24.

25. Banner admits that the Orange Book lists an expiration date for the '467 patent of November 20, 2015. Banner lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 25.

26. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 26.

27. Banner admits that the '976 patent is entitled "Androstenone Derivative," that it states on its face that it issued on December 8, 1998, and that what purports to be a copy of the '976 patent is attached to the Complaint as Exhibit B. Banner denies that the '976 patent was duly and legally issued. Banner lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 27.

28. Paragraph 28 contains legal conclusions to which no answer is required. To the extent that an answer is required, Banner avers that the claims of the '976 patent speak for themselves. Banner denies the remaining allegations of paragraph 28.

29. Banner admits that the Orange Book lists an expiration date for the '976 patent of September 17, 2013. Banner lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 29.

30. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 30.

31. Banner admits that the '427 patent is entitled "Androstenones," that it states on its face that it issued on December 7, 1999, and that what purports to be a copy of the '427 patent is attached to the Complaint as Exhibit C. Banner denies that the '427 patent was duly and legally issued. Banner lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 31.

32. Paragraph 32 contains legal conclusions to which no answer is required. To the extent that an answer is required, Banner avers that the claims of the '427 patent speak for themselves. Banner denies the remaining allegations of paragraph 32.

33. Banner admits that the Orange Book lists an expiration date for the '427 patent of September 17, 2013. Banner lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 33.

34. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 34.

35. Banner admits the allegations of the first sentence of paragraph 35. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of the second sentence of paragraph 35.

36. Paragraph 36 contains legal conclusions to which no answer is required. To the extent that an answer is required, Banner avers that the requirements of 21 U.S.C. § 355(j)(2)(A) speak for themselves. Banner denies the remaining allegations of paragraph 36.

37. Banner admits that in the Banner Notice Letter, Banner notified GSK that the active ingredient in its proposed drug product is dutasteride, that the strength of the proposed drug product is 0.5 mg, and that the dosage form and route of administration of the proposed drug product is an oral capsule. Banner denies the remaining allegations of paragraph 37.

38. Banner admits that in the Banner Notice Letter, Banner notified GSK that its ANDA contained a paragraph IV certification asserting that, in Banner's opinion and to the best of its knowledge, the Patents-in-Suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the dutasteride capsules, 0.5 mg, that are the subject of Banner's ANDA No. 200899. Banner denies the remaining allegations of paragraph 38.

39. Banner denies the allegations of paragraph 39.

40. Banner denies the allegations of paragraph 40.

41. Banner denies the allegations of paragraph 41.

42. Banner denies the allegations of paragraph 42.

43. Banner denies the allegations of paragraph 43.

44. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 44.

45. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 45.

46. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 46.

47. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 47.

48. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 48.

49. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 49.

50. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 50.

51. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 51.

52. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 52.

53. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 53.

54. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 54.

55. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 55.

56. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 56.

57. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 57.

58. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 58.

59. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 59.

60. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 60.

61. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 61.

62. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 62.

63. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 63.

64. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 64.

65. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 65.

66. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 66.

67. In response to paragraph 67, Banner incorporates paragraphs 1-66 above.

68. Banner denies the allegations of paragraph 68.

69. Banner denies the allegations of paragraph 69.

70. Banner denies the allegations of paragraph 70.

71. Banner admits that prior to filing ANDA No. 200899, it was aware of the '467 patent. Banner denies the remaining allegations of paragraph 71.

72. Banner denies the allegations of paragraph 72.

73. In response to paragraph 73, Banner incorporates paragraphs 1-72 above.

74. Banner denies the allegations of paragraph 74.

75. Banner denies the allegations of paragraph 75.

76. Banner denies the allegations of paragraph 76.

77. Banner admits that prior to filing ANDA No. 200899, it was aware of the '976 patent. Banner denies the remaining allegations of paragraph 77.

78. Banner denies the allegations of paragraph 78.

79. In response to paragraph 79, Banner incorporates paragraphs 1-78 above.

80. Banner denies the allegations of paragraph 80.

81. Banner denies the allegations of paragraph 81.

82. Banner denies the allegations of paragraph 82.

83. Banner admits that prior to filing ANDA No. 200899, it was aware of the '427 patent. Banner denies the remaining allegations of paragraph 83.

84. Banner denies the allegations of paragraph 84.

85. In response to paragraph 85, Banner incorporates paragraphs 1-84 above.

86. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 86.

87. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 87.

88. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 88.

89. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 89.

90. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 90.

91. In response to paragraph 91, Banner incorporates paragraphs 1-90 above.

92. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 92.

93. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 93.

94. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 94.

95. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 95.

96. Banner lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 96.

AFFIRMATIVE DEFENSES

97. The claims of the '467, '976 and '427 patents are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103 or 112, or other judicially created bases for invalidation.

98. Upon information and belief, the patent term extension for the '467 patent is invalid due to a material failure to comply with the requirements of 35 U.S.C. § 156.

99. Banner has not infringed any valid claim of the '467, '976 and '427 patents.

100. The Complaint fails to state a claim against Banner upon which relief can be granted.

COUNTERCLAIM

(Declaratory Judgment)

For its counterclaim against GSK, Banner avers as follows:

Parties

101. Banner is a Delaware corporation with a principal place of business in High Point, North Carolina.

102. Upon information and belief, GSK is a Delaware limited liability company with a principal place of business in Philadelphia, Pennsylvania.

Jurisdiction and Venue

103. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

104. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b).

Claim for Relief

105. GSK brought an action against Banner for alleged infringement of the '467, '976 and '427 patents, based on Banner's submission of ANDA No. 200899.

106. The claims of the '467, '976 and '427 patents are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103 or 112, or other judicially created bases for invalidation.

107. Upon information and belief, the patent term extension for the '467 patent is invalid due to a material failure to comply with the requirements of 35 U.S.C. § 156.

108. Banner has not infringed any valid claim of the '467, '976 and '427 patents.

109. The manufacture, use, offer for sale, sale, or importation of the drug product that is the subject of ANDA No. 200899 would not infringe any valid claim of the '467, '976 and '427 patents.

110. An actual and justiciable controversy exists between the parties with respect to validity and infringement of the '467, '976 and '427 patents. Banner is entitled to a declaratory judgment that the '467, '976 and '427 patents are invalid and not infringed.

PRAYER FOR RELIEF

WHEREFORE, Banner prays for a judgment that:

A. Dismisses the Complaint with prejudice;

B. Declares that the claims of the '467, '976 and '427 patents are invalid;

C. Declares that Banner does not infringe any valid claims of the '467, '976 and '427 patents;

D. Declares that the manufacture, use, offer for sale, sale, or importation of the drug product that is the subject of ANDA No. 200899 would not infringe any valid claim of the '467, '976 and '427 patents;

E. Awards Banner its costs and attorneys' fees; and

F. Awards Banner such other and further relief as the Court may deem proper.

Dated: February 4, 2011

PHILLIPS, GOLDMAN & SPENCE, P.A.

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