IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC (f/k/a SMITHKLINE BEECHAM CORPORATION), Plaintiff, v. ANCHEN PHARMACEUTICALS, INC., ANCHEN, INC., and BANNER PHARMACAPS, INC., Defendants.	C.A. No. 1:11-CV-00046-SLR
ANCHEN PHARMACEUTICALS, INC., ANCHEN, INC., and BANNER PHARMACAPS, INC., Counterclaimants, v. GLAXOSMITHKLINE LLC (f/k/a SMITHKLINE BEECHAM CORPORATION), Counterdefendants.	

ANCHEN PHARMACEUTICALS, INC.'S AND ANCHEN, INC.'S ANSWER TO PLAINTIFF'S COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants Anchen Pharmaceuticals, Inc., ("API"), and Anchen Inc. ("AI"), (collectively "Anchen"), hereby answer the Complaint of Plaintiff GlaxoSmithKline LLC ("Complaint") as follows:

NATURE OF ACTION[1]

1. Anchen admits that the Complaint filed by GlaxoSmithKline LLC ("GSK") purports to state an action for patent infringement of United States Patent Nos. 5,565,467 ("the '467 Patent"), 5,846,976 ("the '976 Patent), and 5,998,427 ("the '427 Patent") arising under the patent laws of the United States, Title 35, United States Code.

2. Anchen admits that this action relates to Abbreviated New Drug Application ("ANDA") No. 202530 filed by API for approval to market 0.5 mg dutasteride capsules, a proposed generic version of GSK's AVODART® drug product and ANDA No. 202509 filed by API for approval to market 0.5 mg/0.4 mg dutasteride and tamsulosin capsules, a proposed generic version of GSK's JALYN® drug product. Anchen lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 2 of the Complaint, and therefore denies those allegations.

PARTIES

3. Upon information and belief, Anchen admits that Plaintiff GSK is a Delaware limited liability company having a principal place of business at One Franklin Plaza, Philadelphia, PA 19102. Anchen is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3 of the Complaint, and therefore denies those allegations.

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[1] For the Court's convenience, Anchen has incorporated the "Headings" that appear in the Complaint. It should be understood, however, that Anchen does not necessarily agree with the characterizations of such Headings, and does not waive any right to object to those characterizations.

4. The allegations in Paragraph 4 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4 of the Complaint, and therefore denies those allegations.

5. The allegations in Paragraph 5 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5 of the Complaint, and therefore denies those allegations.

6. Anchen admits the allegations in Paragraph 6 of the Complaint.

7. Anchen admits that API is a corporation organized and existing under the laws of California, having its principal place of business at 9601 Jeronimo Road, Irvine, California 92618. Anchen admits that API markets, sells, and/or distributes, in the United States, including this judicial district, pharmaceutical products developed and/or manufactured by API. Anchen admits that API is a wholly-owned subsidiary of AI. Anchen denies any and all remaining allegations in Paragraph 7 of the Complaint.

8. Anchen admits that API and AI share the same principal place of business. Anchen admits that API markets, sells, and/or distributes, in the United States, pharmaceutical products developed and/or manufactured by API. Anchen denies any and all remaining allegations in Paragraph 8 of the Complaint.

9. Anchen admits that it has represented to the United Stated Patent and Trademark Office, in the context of an application for the federal registration of a trademark, that API and AI constitute a single source to relevant public, with respect to the goods sold or to be sold under that trademark, and that there is unity of control with respect to the nature a quality of the goods

sold or to be sold under that trademark. Anchen denies any and all remaining allegations in Paragraph 9 of the Complaint.

10. Anchen admits that, if ANDA No. 202509 is approved, the dutasteride and tamsulosin hydrochloride ANDA products may be promoted, sold, and/or distributed throughout the United States. Anchen denies any and all remaining allegations in Paragraph 10 of the Complaint.

11. Anchen admits that, if ANDA No. 202530 is approved, the dutasteride ANDA products may be promoted, sold, and/or distributed throughout the United States. Anchen denies any and all remaining allegations in Paragraph 11 of the Complaint.

JURISDICTION AND VENUE

12. Anchen admits the allegations in Paragraph 12 of the Complaint.

13. The allegations in Paragraph 13 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 13 of the Complaint, and therefore denies those allegations.

14. Anchen admits that this Court has personal jurisdiction over AI in this action. Anchen admits that AI is a Delaware corporation. Anchen denies any and all remaining allegations in Paragraph 14 of the Complaint.

15. Anchen admits that this Court has personal jurisdiction over API in this action. Anchen denies any and all remaining allegations in Paragraph 15 of the Complaint.

16. Anchen admits the allegations in Paragraph 16 of the Complaint.

17. Anchen admits that API was a party in Genzyme Corp. v. Anchen Pharmaceuticals, Inc., No. 10-00512-GMS (D. Del.), and that API filed counterclaims seeking

declaratory relief in that action. Anchen denies any and all remaining allegations in Paragraph 17 of the Complaint.

AVODART®

18. Anchen admits that the United States Food and Drug Administration ("FDA") lists GSK as the holder of New Drug Application ("NDA") No. 21319 for AVODART®, the active ingredient of which is dutasteride. Anchen admits that the FDA lists the approval date for NDA No. 21319 as November 20, 2001. Anchen admits that AVODART® is indicated for treatment of symptomatic benign prostate hyperplasia ("BPH") in men with an enlarged prostate. Anchen denies any and all remaining allegations of Paragraph 18.

19. Anchen admits the allegations in Paragraph 19 of the Complaint.

20. Paragraph 20 does not set forth factual allegations requiring a response.

JAYLN®

21. Anchen admits that the FDA lists GSK as the holder of NDA No. 22460 for JALYN®, the active ingredients of which are dutasteride and tamsulosin hydrochloride. Anchen admits that the FDA lists the approval date for NDA No. 22460 as June 14, 2010. Anchen admits that JALYN® is indicated for treatment of symptomatic BPH in men with an enlarged prostate. Anchen denies any and all remaining allegations of Paragraph 21.

22. Anchen admits the allegations in Paragraph 22 of the Complaint.

THE PATENTS-IN-SUIT

23. Anchen admits that Exhibit A to the Complaint purports to be a copy of the '467 Patent. Anchen admits that the '467 Patent states, on its face, that (i) it was issued on October 15, 1996 to Glaxo Wellcome Inc. as assignee, and (ii) it is entitled "Androstenone Derivative."

Anchen lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23 of the Complaint, and therefore denies those allegations.

24. Anchen admits that the Claim 1 of the '467 Patent claims "17β-N-(2,5-bis(Trifluoromethyl))phenylcarbamoyl-4-aza-5α-androst-1-en-3-one or a pharmaceutically acceptable solvate thereof," and that the remaining claims of the '467 Patent, Claims 2–10, recite "pharmaceutical formulation[s]." Anchen denies any and all remaining allegations in Paragraph 24 of the Complaint.

25. Anchen admits that a Certificate Extending Patent Term Under 35 U.S.C. § 156 purports to extend the term of the '467 Patent for 766 days, subject to the provisions of 35 U.S.C. § 156. Anchen admits that the Certificate Extending Patent Term Under 35 U.S.C. § 156 indicates that the original expiration date for the '467 Patent was October 15, 2013. Anchen admits that the date that is 766 days from October 15, 2013, is November 20, 2015. Anchen denies any and all remaining allegations in Paragraph 25 of the Complaint.

26. Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 26 of the Complaint, and therefore denies those allegations.

27. The allegations in Paragraph 27 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 27 of the Complaint, and therefore denies those allegations.

28. The allegations in Paragraph 28 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 28 of the Complaint, and therefore denies those allegations.

29. The allegations in Paragraph 29 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 29 of the Complaint, and therefore denies those allegations.

30. The allegations in Paragraph 30 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 30 of the Complaint, and therefore denies those allegations.

31. The allegations in Paragraph 31 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 31 of the Complaint, and therefore denies those allegations.

32. The allegations in Paragraph 32 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 32 of the Complaint, and therefore denies those allegations.

33. The allegations in Paragraph 33 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 33 of the Complaint, and therefore denies those allegations.

34. The allegations in Paragraph 34 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a

response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 34 of the Complaint, and therefore denies those allegations.

INFRINGEMENT BY BANNER

35. The allegations in Paragraph 35 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 35 of the Complaint, and therefore denies those allegations.

36. The allegations in Paragraph 36 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 36 of the Complaint, and therefore denies those allegations.

37. The allegations in Paragraph 37 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 37 of the Complaint, and therefore denies those allegations.

38. The allegations in Paragraph 38 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 38 of the Complaint, and therefore denies those allegations.

39. The allegations in Paragraph 39 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 39 of the Complaint, and therefore denies those allegations.

40. The allegations in Paragraph 40 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 40 of the Complaint, and therefore denies those allegations.

41. The allegations in Paragraph 41 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 41 of the Complaint, and therefore denies those allegations.

42. The allegations in Paragraph 42 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 42 of the Complaint, and therefore denies those allegations.

43. The allegations in Paragraph 43 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 43 of the Complaint, and therefore denies those allegations.

44. The allegations in Paragraph 44 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 44 of the Complaint, and therefore denies those allegations.

INFRINGEMENT BY ANCHEN (AVODART®)

45. Anchen admits that API notified GSK, pursuant to 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act ("FDCA"), by a letter dated December 28, 2010 ("the

AVODART® Notice Letter"), of API's filing of ANDA No. 202530. Anchen admits that ANDA No. 202530 relates to 0.5 mg dutasteride capsule drug products. Anchen admits that the AVODART® Notice Letter included a statement that ANDA No. 202530 contained a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV ("Paragraph IV Certification"). Anchen denies any and all remaining allegations in Paragraph 45 of the Complaint.

46. Anchen admits that API has submitted and the FDA has received ANDA No. 202530 under FDCA Section 505(j)(2)(B)(ii). Anchen denies any and all remaining allegations in Paragraph 46 of the Complaint.

47. Anchen admits that API has submitted and the FDA has received ANDA No. 202530 under FDCA Section 505(j)(2)(B)(ii) which contains the required bioavailability or bioequivalence data in order to obtain approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of the drug product containing dutasteride. Anchen denies any and all remaining allegations in Paragraph 47 of the Complaint.

48. Anchen admits that the AVODART® Notice Letter states that API's proposed drug product is in the form of a capsule which contains the equivalent of 0.5 mg of dutasteride as the active ingredient. Anchen denies any and all remaining allegations in Paragraph 48 of the Complaint.

49. Anchen admits that the AVODART® Notice Letter states that ANDA No. 202530 contains a Paragraph IV Certification with respect to the '467 Patent, that in the opinion of API and to the best of its knowledge, no valid, enforceable claim of the '467 Patent will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which ANDA

No. 202530 has been submitted. Anchen denies any and all remaining allegations in Paragraph 49 of the Complaint.

50. Anchen admits that the AVODART® Notice Letter enclosed a detailed statement of the factual and legal bases for API's Paragraph IV Certification, that in the opinion of API and to the best of its knowledge, no valid, enforceable claim of the '467 Patent will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which ANDA No. 202530 has been submitted. Anchen denies any and all remaining allegations in Paragraph 50 of the Complaint.

51. Anchen denies the allegations in Paragraph 51 of the Complaint.

52. Anchen denies the allegations in Paragraph 52 of the Complaint.

53. Anchen denies the allegations in Paragraph 53 of the Complaint.

54. Anchen denies the allegations in Paragraph 54 of the Complaint.

55. Anchen admits that the Complaint was filed on January 13, 2011, a date that is less than 45 days from the date that GSK received the AVODART® Notice Letter. Anchen denies any and all remaining allegations in Paragraph 55 of the Complaint.

INFRINGEMENT BY ANCHEN (JALYN®)

56. Anchen admits that API notified GSK, pursuant to 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act ("FDCA"), by a letter dated December 28, 2010 ("the AVODART® Notice Letter"), of API's filing of ANDA No. 202509. Anchen admits that ANDA No. 202530 relates to dutasteride and tamsulosin hydrochloride capsule drug products, 0.5 mg/0.4 mg. Anchen admits that the JALYN® Notice Letter included a statement that ANDA No. 202509 contained a certification under FDCA Section 505(j)(2)(A)(vii), Paragraph IV

("Paragraph IV Certification"). Anchen denies any and all remaining allegations in Paragraph 56 of the Complaint.

57. Anchen admits that API has submitted and the FDA has received ANDA No. 202509 under FDCA Section 505(j)(2)(B)(ii). Anchen denies any and all remaining allegations in Paragraph 57 of the Complaint.

58. Anchen admits that API has submitted and the FDA has received ANDA No. 202509 under FDCA Section 505(j)(2)(B)(ii) which contains the required bioavailability or bioequivalence data in order to obtain approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of the drug product containing dutasteride and tamsulosin hydrochloride. Anchen denies any and all remaining allegations in Paragraph 58 of the Complaint.

59. Anchen admits that the JALYN® Notice Letter states that API's proposed drug product is in the form of a capsule which contains the equivalent of 0.5 mg of dutasteride and 0.4 mg of tamsulosin hydrochloride as the active ingredients. Anchen denies any and all remaining allegations in Paragraph 59 of the Complaint.

60. Anchen admits that the JALYN® Notice Letter states that ANDA No. 202509 contains a Paragraph IV certification with respect to the '467 Patent, that in the opinion of API and to the best of its knowledge, no valid, enforceable claim of the '467 Patent will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which ANDA No. 202509 has been submitted. Anchen denies any and all remaining allegations in Paragraph 60 of the Complaint.

61. Anchen admits that the JALYN® Notice Letter enclosed a detailed statement of the factual and legal bases for API's Paragraph IV Certification, that in the opinion of API and to

the best of its knowledge, no valid, enforceable claim of the '467 Patent will be infringed by the manufacture, importation, use, sale, or offer for sale of the drug product for which ANDA No. 202509 has been submitted. Anchen denies any and all remaining allegations in Paragraph 61 of the Complaint.

62. Anchen denies the allegations in Paragraph 62 of the Complaint.

63. Anchen denies the allegations in Paragraph 63 of the Complaint.

64. Anchen denies the allegations in Paragraph 64 of the Complaint.

65. Anchen denies the allegations in Paragraph 65 of the Complaint.

66. Anchen admits that the Complaint was filed on January 13, 2011, a date that is less than 45 days from the date that GSK received the JALYN® Notice Letter. Anchen denies any and all remaining allegations in Paragraph 66 of the Complaint.

COUNT ONE: INFRINGEMENT OF THE '467 PATENT (Banner)

67. Anchen repeats and realleges its responses to the allegations in Paragraphs 1–66 of the Complaint, as set forth in Paragraphs 1–66 of this Answer, as though fully set forth herein.

68. The allegations in Paragraph 68 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 68 of the Complaint, and therefore denies those allegations.

69. The allegations in Paragraph 69 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 69 of the Complaint, and therefore denies those allegations.

70. The allegations in Paragraph 70 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 70 of the Complaint, and therefore denies those allegations.

71. The allegations in Paragraph 71 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 71 of the Complaint, and therefore denies those allegations.

72. The allegations in Paragraph 72 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 72 of the Complaint, and therefore denies those allegations.

COUNT TWO: INFRINGEMENT OF THE '976 PATENT (Banner)

73. The allegations in Paragraph 73 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 73 of the Complaint, and therefore denies those allegations.

74. The allegations in Paragraph 74 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 74 of the Complaint, and therefore denies those allegations.

75. The allegations in Paragraph 75 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a

response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 75 of the Complaint, and therefore denies those allegations.

76. The allegations in Paragraph 76 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 76 of the Complaint, and therefore denies those allegations.

77. The allegations in Paragraph 77 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 77 of the Complaint, and therefore denies those allegations.

78. The allegations in Paragraph 78 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 78 of the Complaint, and therefore denies those allegations.

COUNT THREE: INFRINGEMENT OF THE '427 PATENT (Banner)

79. The allegations in Paragraph 79 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 79 of the Complaint, and therefore denies those allegations.

80. The allegations in Paragraph 80 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 80 of the Complaint, and therefore denies those allegations.

81. The allegations in Paragraph 81 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 81 of the Complaint, and therefore denies those allegations.

82. The allegations in Paragraph 82 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 82 of the Complaint, and therefore denies those allegations.

83. The allegations in Paragraph 83 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 83 of the Complaint, and therefore denies those allegations.

84. The allegations in Paragraph 84 of the Complaint do not relate to the cause of action against Anchen, and therefore no response from Anchen is required. To the extent a response is required, Anchen lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 84 of the Complaint, and therefore denies those allegations.

COUNT FOUR: INFRINGEMENT OF THE '467 PATENT (Anchen No. 20-2530)

85. Anchen repeats and realleges its responses to the allegations in Paragraphs 1–84 of the Complaint, as set forth in Paragraphs 1–84 of this Answer, as though fully set forth herein.

86. Anchen denies the allegations in Paragraph 86 of the Complaint.

87. Anchen denies the allegations in Paragraph 87 of the Complaint.

88. Anchen denies the allegations in Paragraph 88 of the Complaint.

89. Anchen denies the allegations in Paragraph 89 of the Complaint.

90. Anchen denies the allegations in Paragraph 90 of the Complaint.

COUNT FIVE: INFRINGEMENT OF THE '467 PATENT (Anchen No. 20-2509)

91. Anchen repeats and realleges its responses to the allegations in Paragraphs 1–90 of the Complaint, as set forth in Paragraphs 1–90 of this Answer, as though fully set forth herein.

92. Anchen denies the allegations in Paragraph 92 of the Complaint.

93. Anchen denies the allegations in Paragraph 93 of the Complaint.

94. Anchen denies the allegations in Paragraph 94 of the Complaint.

95. Anchen denies the allegations in Paragraph 95 of the Complaint.

96. Anchen denies the allegations in Paragraph 96 of the Complaint.

AFFIRMATIVE DEFENSES

Anchen sets forth the following affirmative and other defenses. Anchen does not intend hereby to assume the burden of proof with respect to those matters on which, under law, GSK bears the burden.

First Affirmative Defense – Noninfringement of the '467 Patent

97. Anchen does not infringe any valid and enforceable claim of the '467 Patent.

Second Affirmative Defense – Invalidity of the '467 Patent

98. The claims of '467 Patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code, are invalid under the doctrine of non-statutory double patenting, and/or are invalid under any other ground provided by 35 U.S.C. § 282.

99. The extension of the Patent Term of the '467 Patent is invalid under Section 282, fourth paragraph, of Title 35 of the United States Code.

COUNTERCLAIMS

Defendants Anchen Pharmaceuticals, Inc., ("API"), and Anchen Inc. ("AI"), (collectively "Anchen"), hereby assert their Counterclaims against of Plaintiff GlaxoSmithKline LLC ("GSK") as follows:

PARTIES

100. Counterclaimant API is a corporation organized and existing under the laws of California, having its principal place of business at 9601 Jeronimo Road, Irvine, California 92618. Counterclaimant AI is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9601 Jeronimo Road, Irvine, California 92618. API is a wholly-owned subsidiary of AI.

101. On information and belief, Counterdefendant GSK is a Delaware limited liability company having a principal place of business at One Franklin Plaza, Philadelphia, PA 19102,

JURISDICTION AND VENUE

102. This is an action for declaratory judgment that United States Patent No. 5,565,467 ("the '467 Patent") is invalid and/or not infringed by the products in Anchen's Abbreviated New Drug Application ("ANDA") No. 202530 and ANDA No. 202509.

103. This action is based upon an actual controversy between the parties concerning the invalidity and/or noninfringement of the '467 Patent, and Anchen's right to continue to seek approval of ANDA No. 202530 and ANDA No. 202509, and upon approval by the United States Food and Drug Administration ("FDA"), to manufacture, import, use, sell and/or offer to sell its 0.5 mg dutasteride and its 0.5 mg/0.4 mg dutasteride and tamsulosin ANDA products in the United States.

104. This Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. § 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271(e)(2).

105. Venue is proper under 28 U.S.C. § 1391 and 1400(b), and by GSK's choice of forum.

106. API has submitted, and is continuing to seek FDA approval of, ANDA No. 202530 and directed to a product containing dutasteride, a generic version of GSK's AVODART® product. API's ANDA seeks approval for API to engage in the commercial manufacture, use and sale of a product containing dutasteride, which GSK alleges infringes the '467 Patent.

107. API has submitted, and is continuing to seek FDA approval of, ANDA No. 202509 and directed to a product containing dutasteride and tamsulosin, a generic version of GSK's JALYN® product. API's ANDA seeks approval for API to engage in the commercial manufacture, use and sale of a product containing dutasteride and tamsulosin, which GSK alleges infringes the '467 Patent.

108. On information and belief, GSK owns by assignment, the '467 Patent, which is entitled "Androstenone Derivative." The '467 Patent lists, on its face, Kenneth W. Batchelor, Stephen V. Frye, George F. Dorsey, Jr., and Robert A. Mook, Jr., as inventors. United States Patent and Trademark Office records indicate that Kenneth W. Batchelor and Stephen V. Frye are now listed as the inventors of the'467 Patent. A copy of the '467 Patent is attached hereto as Exhibit A.

109. In view of the foregoing, a conflict of asserted rights has arisen between Anchen and GSK with respect to the infringement, validity, and/or enforceability of the relevant claims of the '467 Patent, and as to API's right to obtain FDA approval to engage in the commercial

manufacture, importation, use, offer for sale, and/or sale of its dutasteride and dutasteride/tamsulosin ANDA products. An actual controversy exists between Anchen and GSK.

FIRST COUNTERCLAIM – DECLARATION OF INVALIDITY

110. Anchen repeats and realleges Paragraphs 99–109 as if set forth specifically herein.

111. The claims of '467 Patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code, are invalid under the doctrine of non-statutory double patenting, and/or are invalid under any other ground provided by 35 U.S.C. § 282.

112. The extension of the Patent Term of the '467 Patent is invalid under Section 282, fourth paragraph, of Title 35 of the United States Code.

SECOND COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT

113. Anchen repeats and realleges Paragraphs 99–112 as if set forth specifically herein.

114. Anchen does not infringe any valid and enforceable claim of the '467 Patent.

THIRD COUNTERCLAIM – EXCEPTIONAL CASE

115. Anchen repeats and realleges Paragraphs 99–114 as if set forth specifically herein.

116. This case is exceptional under 35 U.S.C. § 285. Therefore, Counterdefendants should be ordered to pay Anchen's reasonable attorneys' fees and costs under 35 U.S.C. § 285.

DEMAND FOR JUDGMENT

WHEREFORE, Anchen prays for the following relief:

A. That all claims against Anchen be dismissed with prejudice and that all relief requested by GSK be denied;

B. That a judgment be entered declaring that Anchen has not, and does not, infringe any valid claim of the '467 Patent, that Anchen has a lawful right to obtain FDA approval of ANDA No. 202530 for its 0.5 mg dutasteride products, and further that Anchen has a lawful right to manufacture, import, use, sell and/or offer to sell its 0.5 mg strength dutasteride ANDA products once approved by the FDA;

C. That a judgment be entered declaring that Anchen has not, and does not, infringe any valid claim of the '467 Patent, that Anchen has a lawful right to obtain FDA approval of ANDA No. 202509 for its 0.5 mg/0.4 mg dutasteride and tamsulosin products, and further that Anchen has a lawful right to manufacture, import, use, sell and/or offer to sell its 0.5 mg/0.4 mg dutasteride and tamsulosin ANDA products once approved by the FDA;

D. That a judgment be entered declaring that the claims of the '467 Patent are invalid;

E. That Plaintiffs/Counterdefendants and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Anchen or any of its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Anchen, or charging any of them either orally or in writing with infringement of the '467 Patent;

F. That a judgment be entered declaring this action to be an exceptional case within the meaning of 35 U.S.C. § 285, and that Anchen is entitled to recover its reasonable attorneys' fees upon prevailing in this action; and

G. That Anchen be awarded such other and further relief as is just and proper.

PHILLIPS, GOLDMAN & SPENCE, P.A.

By: */s/ John C. Phillips, Jr.*
John C. Phillips, Jr., Esq. (No. 110)
Megan C. Haney (No. 5016)
1200 North Broom Street
Wilmington, Delaware 19806
(302) 655-4200 Main Number
(302) 655-4210 Facsimile
jcp@pgslaw.com

Dated: February 4, 2011

Attorneys for Defendants,
Anchen Pharmaceuticals, Inc., and Anchen Inc.

OF COUNSEL:

William R. Zimmerman, Esq.
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Avenue, NW, Suite 900
Washington, DC 20006
Telephone: (202) 640-6400
Facsimile: (202) 640-6401
bzimmerman@kmob.com

Payson LeMeilleur, Esq.
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Telephone: (949) 760-0404
Facsimile: (949) 760-9502
plemeilleur@kmob.com

CERTIFICATE OF SERVICE

It is hereby certified that the undersigned has this day served a true and correct copy of Anchen Pharmaceuticals, Inc.'s and Anchen, Inc.'s Answer to Plaintiff's Complaint, Affirmative Defenses and Counterclaims on the following counsel as indicated below:

BY CM/ECF and EMAIL

Jack B. Blumenfeld
Derek James Fahnestock
Morris, Nichols, Arsht & Tunnell
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
dfahnestock@mnat.com

BY EMAIL

William F. Lee
Lisa J. Pirozzolo
Christopher R. Noyes
Wilmer Hale LLP
60 State Street
Boston, MA 02109
william.lee@wilmerhale.com
lisa.pirozzolo@wilmerhale.com
christopher.noyes@wilmerhale.com

Dated: February 4, 2011

/s/ John C. Phillips, Jr.
John C. Phillips, Jr., Esq.