IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC (f/k/a SMITHKLINE BEECHAM CORPORATION),	)	
Plaintiff,	)	
v.	)	C.A. No. _____
ANCHEN PHARMACEUTICALS, INC., ANCHEN, INC. and BANNER PHARMACAPS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff GlaxoSmithKline LLC (formerly known as SmithKline Beecham Corporation) ("Plaintiff" or "GSK"), for its Complaint against Defendants Anchen Pharmaceuticals, Inc. ("API"), Anchen, Inc. ("Anchen Inc.") (collectively, "Anchen"), and Banner Pharmacaps, Inc. ("Banner") (collectively, "Defendants"), upon personal knowledge as to its own actions and upon information and belief as to the actions of others, hereby alleges as follows:

NATURE OF ACTION

1. This is an action for patent infringement of U.S. 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, 35 U.S.C. §§ 271 and 281.

2. This action relates to the following three Abbreviated New Drug Applications ("ANDA") filed with the U.S. Food and Drug Administration ("FDA"):

- ANDA No. 20-0899 filed by Banner for approval to market 0.5 mg dutasteride capsules, a proposed generic version of GSK's AVODART® drug product;

- ANDA No. 20-2530 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. 20-2509 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.

PARTIES

3. Plaintiff GSK is a Delaware limited liability company having a principal place of business at One Franklin Plaza, Philadelphia, PA 19102. GSK is a research-based pharmaceutical company.

4. Upon information and belief, Defendant Banner is a corporation organized and existing under the laws of Delaware, with a principal place of business at 4100 Mendenhall Oaks Parkway, Suite 301, High Point, North Carolina 27265. According to its website (www.banpharm.com), Banner is a "global gelatin-based drug delivery and specialty pharmaceutical company."

5. Upon information and belief, following any FDA approval of ANDA No. 20-0899, Banner will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 20-0899 throughout the United States, and/or import such generic products into the United States.

6. Upon information and belief, Defendant Anchen Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9601 Jeronimo Road, Irvine, California 92618.

7. Upon information and belief, Defendant 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. Upon information and belief, API is engaged in the manufacture and sale of pharmaceutical products throughout the United States, including Delaware. API is a wholly-owned subsidiary of Anchen Inc.

8. Upon information and belief, API and Anchen Inc. act in concert with respect to the development, manufacturing, marketing, and sale of generic copies of branded pharmaceutical products for the U.S. market. Upon information and belief, API and Anchen Inc. share the same principal place of business and have at least one officer and/or director in common.

9. Upon information and belief, Anchen has represented to the United States Patent and Trademark Office that API and Anchen Inc. "constitute a single source to the relevant public, and there is unity of control with respect to the nature and quality of the goods."

10. Upon information and belief, following any FDA approval of ANDA No. 20-2509, API and Anchen Inc. will work in concert to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 20-2509 throughout the United States, and/or import such generic products into the United States.

11. Upon information and belief, following any FDA approval of ANDA No. 20-2530, API and Anchen Inc. will work in concert to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 20-2530 throughout the United States, and/or import such generic products into the United States.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 100, et seq. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court pursuant to 28 U.S.C. § 1391(c) and 28 U.S.C. § 1400(b).

13. This Court has personal jurisdiction over Banner because Banner is a resident and citizen of Delaware and has availed itself of the rights and benefits of the laws of Delaware by incorporating in Delaware and engaging in systematic and continuous contacts with Delaware. In addition, upon information and belief, Banner has previously availed itself of this forum for the purpose of litigating patent disputes. For example, in 2008, Banner filed a counterclaim seeking a declaratory judgment of noninfringement in *Abbott Laboratories v. Banner Pharmacaps Inc.*, No. 07-754-GMS (D. Del.).

14. This Court has personal jurisdiction over Anchen Inc. because Anchen Inc. is a resident and citizen of Delaware and has availed itself of the rights and benefits of the laws of Delaware by incorporating in Delaware and engaging in systematic and continuous contacts with Delaware.

15. This Court has personal jurisdiction over API because API regularly and continuously transacts business within Delaware. Upon information and belief, API, either directly and/or in concert with Anchen Inc., markets and sells pharmaceutical products throughout the United States, including in Delaware. API either directly and/or under the direction of Anchen Inc. derives substantial revenue from sales of its products in Delaware and has availed itself of the privilege of conducting business within Delaware. Upon information

and belief, API sold at least $1,079,202 worth of drug products in Delaware between June 2007 and May 2009.

16. This Court previously determined that it has personal jurisdiction over API and Anchen Inc. in its March 12, 2010 decision in *In re: Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, MDL No. 09-2118 (Dkt. No. 25). In particular, the Court determined that it had general jurisdiction over API. (*See id.* at 20).

17. In addition, upon information and belief, API has previously availed itself of this forum for the purpose of litigating patent disputes. For example, in 2010, API filed counterclaims seeking a declaratory judgment of noninfringement, unenforceability, and/or invalidity in *Genzyme Corp. v. Anchen Pharmaceuticals, Inc.*, No. 10-00512-GMS (D. Del.).

AVODART®

18. GSK holds approved New Drug Application ("NDA") No. 21-319 for AVODART®, the active ingredient of which is dutasteride. AVODART® was approved by the FDA on November 20, 2001. AVODART® capsules are used for the treatment of symptomatic benign prostatic hyperplasia ("BPH")—essentially, enlargement of the prostate gland.

19. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the following patents are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to AVODART®: the '467 Patent, the '976 Patent, and the '427 Patent.

20. The '467 Patent, '976 Patent, and '427 Patent are collectively referred to herein as the "Patents-in-Suit."

JALYN®

21. GSK holds approved NDA No. 22-460 for JALYN®, the active ingredients of which are dutasteride and tamsulosin. JALYN® was approved by the FDA on June 14, 2010. JALYN® capsules are used for the treatment of symptomatic BPH.

22. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the following patents are listed in the Orange Book with respect to JALYN®: the '467 Patent, the '976 Patent, and the '427 Patent.

THE PATENTS-IN-SUIT

23. GSK is the owner of the '467 Patent, entitled "Androstenone Derivative," which was duly and legally issued on October 15, 1996. The original assignee, Glaxo Wellcome Inc., assigned the '467 Patent to GSK effective March 30, 2001. A true and complete copy of the '467 Patent is attached hereto as **Exhibit A**.

24. The '467 Patent, *inter alia*, claims a compound (dutasteride) and various formulations useful in treating BPH and other androgen responsive conditions.

25. The '467 Patent expires on November 20, 2015.

26. GSK is the owner of the entire right, title and interest in the '467 Patent and possesses the right to sue for infringement of the '467 Patent.

27. GSK is the owner of the '976 Patent, entitled "Androstenone Derivative," which was duly and legally issued on December 8, 1998. The original assignee, Glaxo Wellcome Inc., assigned the '976 Patent to GSK effective March 30, 2001. A true and complete copy of the '976 patent is attached hereto as **Exhibit B**.

28. The '976 Patent, *inter alia*, claims methods of treating BPH and other androgen responsive conditions by administering dutasteride.

29. The '976 Patent expires on September 17, 2013.

30. GSK is the owner of the entire right, title and interest in the '976 Patent and possesses the right to sue for infringement of the '976 Patent.

31. GSK is the owner of the '427 Patent, entitled "Androstenones," which was duly and legally issued on December 7, 1999. The original assignee, Glaxo Wellcome Inc., assigned the '427 Patent to GSK effective March 30, 2001. A true and complete copy of the '427 Patent is attached hereto as **Exhibit C**.

32. The '427 Patent generally claims various compounds useful as testosterone 5α-reductase inhibitors, including dutasteride, and processes for preparing them. It also claims, *inter alia*, methods of treating BPH by administering the claimed compounds.

33. The '427 Patent expires on September 17, 2013.

34. GSK is the owner of the entire right, title and interest in the '427 Patent and possesses the exclusive right to sue for infringement of the '427 Patent.

INFRINGEMENT BY BANNER

35. By letter dated November 29, 2010 ("the Banner Notice Letter"), Banner notified GSK that it had submitted ANDA No. 20-0899 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of generic 0.5 mg dutasteride capsules before the expiration of the Patents-in-Suit. Upon information and belief, Banner intends to engage in commercial manufacture, use, and sale of generic 0.5 mg dutasteride capsules promptly upon receiving FDA approval to do so.

36. By filing ANDA No. 20-0899, Banner has necessarily represented to the FDA that the components of its proposed generic 0.5 mg dutasteride capsules have the same

active ingredients as those of the corresponding components of AVODART®, have the same route of administration, dosage form, and strengths as the corresponding components of AVODART®, and are bioequivalent to the corresponding components of AVODART®.

37. In the Banner Notice Letter, Banner notified GSK that, like AVODART®, the active ingredient in its proposed drug product is dutasteride, the strength of its proposed drug product is 0.5 mg, and the dosage form and route of administration of its proposed drug product is an oral capsule.

38. In the Banner Notice Letter, Banner notified GSK that its ANDA contained a "Paragraph IV certification" asserting that, in Banner's opinion, certain claims of the Patents-in-Suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Banner's proposed generic 0.5 mg dutasteride capsules.

39. The Banner Notice Letter does not contend that Banner's proposed generic 0.5 mg dutasteride capsules will not infringe claims 1-3 of the '467 Patent, claims 1-3 of the '976 Patent, and claims 1-6 and 8-17 of the '427 Patent.

40. Banner has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 20-0899 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of generic dutasteride capsules before the expiration of the respective terms of each of the Patents-in-Suit.

41. The commercial manufacture, use, offer for sale, sale and/or importation of the proposed generic dutasteride capsules for which Banner seeks approval in its ANDA will infringe one or more claims of the Patents-in-Suit.

42. The sale or offer for sale of the proposed generic dutasteride capsules for which Banner seeks approval in its ANDA will actively induce infringement and/or contributorily infringe one or more claims of the Patents-in-Suit.

43. GSK is entitled under 35 U.S.C. § 271(e)(4) to full relief from Banner's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 20-0899 relating to Banner's proposed generic dutasteride capsules shall not be earlier than the expiration of the Patents-in-Suit.

44. This Complaint is being filed before the expiration of the forty-five day period from the date GSK received the Banner Notice Letter.

INFRINGEMENT BY ANCHEN (AVODART®)

45. By letter dated December 28, 2010 ("the Anchen AVODART® Notice Letter"), API notified GSK that it had submitted ANDA No. 20-2530 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of generic 0.5 mg dutasteride capsules before the expiration of the '467 Patent. Upon information and belief, API and/or Anchen Inc. intends to engage in commercial manufacture, use, and sale of generic 0.5 mg dutasteride capsules promptly upon receiving FDA approval to do so.

46. Upon information and belief, Anchen Inc. initiates, directs, and controls the activities of API with regard to ANDA No. 20-2530 and the proposed generic dutasteride capsules described therein. Upon information and belief, Anchen Inc., through API as its agent, initiated, directed, and controlled the preparation and filing of ANDA No. 20-2530 with the FDA.

47. By filing ANDA No. 20-2530, Anchen has necessarily represented to the FDA that the components of its proposed generic 0.5 mg dutasteride capsules have the same active ingredients as those of the corresponding components of AVODART®, have the same route of administration, dosage form, and strengths as the corresponding components of AVODART®, and are bioequivalent to the corresponding components of AVODART®.

48. In the Anchen AVODART® Notice Letter, Anchen notified GSK that, like AVODART®, the active ingredient in its proposed drug product is dutasteride, the strength of its proposed drug product is 0.5 mg, and the dosage form and route of administration of its proposed drug product is an oral capsule.

49. In the Anchen AVODART® Notice Letter, Anchen notified GSK that its ANDA contained a "Paragraph IV certification" asserting that, in Anchen's opinion, certain claims of the '467 Patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Anchen's proposed generic 0.5 mg dutasteride capsules.

50. The Anchen AVODART® Notice Letter does not contend that Anchen's proposed generic 0.5 mg dutasteride capsules will not infringe claims 1-3 of the '467 Patent.

51. By filing ANDA No. 20-2530 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of generic dutasteride capsules before the expiration of the '467 Patent, Anchen has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2).

52. The commercial manufacture, use, offer for sale, sale and/or importation of the proposed generic dutasteride capsules for which Anchen seeks approval in its ANDA will infringe one or more claims of the '467 Patent.

53. The sale or offer for sale of the proposed generic dutasteride capsules for which Anchen seeks approval in its ANDA will actively induce infringement and/or contributorily infringe one or more claims of the '467 Patent.

54. GSK is entitled under 35 U.S.C. § 271(e)(4) to full relief from Anchen's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 20-2530 relating to Anchen's generic dutasteride capsules shall not be earlier than the expiration of the '467 Patent.

55. This Complaint is being filed before the expiration of the forty-five day period from the date GSK received the Anchen AVODART® Notice Letter.

INFRINGEMENT BY ANCHEN (JALYN®)

56. By letter dated December 29, 2010 ("the Anchen JALYN® Notice Letter"), API notified GSK that it had submitted ANDA No. 20-2509 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, and sale of generic 0.5 mg/0.4 mg dutasteride and tamsulosin capsules before the expiration of the '467 Patent. Upon information and belief, API and/or Anchen Inc. intends to engage in commercial manufacture, use, and sale of generic 0.5 mg/0.4 mg dutasteride and tamsulosin capsules promptly upon receiving FDA approval to do so.

57. Upon information and belief, Anchen Inc. initiates, directs, and controls the activities of API with regard to ANDA No. 20-2509 and the proposed generic dutasteride and tamsulosin capsules described therein. Upon information and belief, Anchen Inc., through API as its agent, initiated, directed, and controlled the preparation and filing of ANDA No. 20-2509 with the FDA.

58. By filing ANDA No. 20-2509, Anchen has necessarily represented to the FDA that the components of its proposed generic 0.5 mg/0.4 mg dutasteride and tamsulosin capsules have the same active ingredients as those of the corresponding components of JALYN®, have the same route of administration, dosage form, and strengths as the corresponding components of JALYN®, and are bioequivalent to the corresponding components of JALYN®.

59. In the Anchen JALYN® Notice Letter, Anchen notified GSK that, like JALYN®, the active ingredients in its proposed drug product are dutasteride and tamsulosin, the strength of its proposed drug product is 0.5 mg/0.4 mg, and the dosage form and route of administration of its proposed drug product is an oral capsule.

60. In the Anchen JALYN® Notice Letter, Anchen notified GSK that its ANDA contained a "Paragraph IV certification" asserting that, in Anchen's opinion, certain claims of the '467 Patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Anchen's proposed generic 0.5 mg/0.4 mg dutasteride and tamsulosin capsules.

61. The Anchen JALYN® Notice Letter does not contend that Anchen's proposed generic 0.5 mg/0.4 mg dutasteride and tamsulosin capsules will not infringe claims 1-5 of the '467 Patent.

62. By filing ANDA No. 20-2509 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of generic dutasteride and tamsulosin capsules before the expiration of the '467 Patent, Anchen has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2).

63. The commercial manufacture, use, offer for sale, sale and/or importation of the proposed generic dutasteride and tamsulosin capsules for which Anchen seeks approval in its ANDA will infringe one or more claims of the '467 Patent.

64. The sale or offer for sale of the proposed generic dutasteride and tamsulosin capsules for which Anchen seeks approval in its ANDA will actively induce infringement and/or contributorily infringe one or more claims of the '467 Patent.

65. GSK is entitled under 35 U.S.C. § 271(e)(4) to full relief from Anchen's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 20-2509 relating to Anchen's proposed generic dutasteride and tamsulosin capsules shall not be earlier than the expiration of the '467 Patent.

66. This Complaint is being filed before the expiration of the forty-five day period from the date GSK received the Anchen JALYN® Notice Letter.

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

67. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-66 of this Complaint.

68. Banner's submission of ANDA No. 20-0899 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic dutasteride capsules before the expiration of the '467 Patent constitutes infringement of one or more of the claims of the '467 patent under 35 U.S.C. § 271(e)(2)(A).

69. Upon FDA approval of ANDA No. 20-0899, Banner will further infringe the '467 Patent by making, using, offering to sell, and selling generic dutasteride capsules in the United States and/or importing such tablets into the United States, and by actively inducing

and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

70. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Banner will actively encourage and/or instruct others on how to use its proposed generic dutasteride capsules in a way that infringes at least one claim of the '467 Patent. Upon information and belief, Banner will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '467 Patent.

71. Upon information and belief, Banner had actual and constructive knowledge of the '467 Patent prior to filing ANDA No. 20-0899 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '467 Patent.

72. If Banner's infringement of the '467 patent is not enjoined, GSK will suffer substantial and irreparable harm for which there is no remedy at law.

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

73. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-72 of this Complaint.

74. Banner's submission of ANDA No. 20-0899 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic dutasteride capsules before the expiration of the '976 Patent constitutes infringement of one or more of the claims of the '976 patent under 35 U.S.C. § 271(e)(2)(A).

75. Upon FDA approval of ANDA No. 20-0899, Banner will further infringe the '976 Patent by making, using, offering to sell, and selling generic dutasteride capsules in the United States and/or importing such tablets into the United States, and by actively inducing and

contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

76. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Banner will actively encourage and/or instruct others on how to use its proposed generic dutasteride capsules in a way that infringes at least one claim of the '976 Patent. Upon information and belief, Banner will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '976 Patent.

77. Upon information and belief, Banner had actual and constructive knowledge of the '976 Patent prior to filing ANDA No. 20-0899 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '976 Patent.

78. If Banner's infringement of the '976 patent is not enjoined, GSK will suffer substantial and irreparable harm for which there is no remedy at law.

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

79. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-78 of this Complaint.

80. Banner's submission of ANDA No. 20-0899 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic dutasteride capsules before the expiration of the '427 Patent constitutes infringement of one or more of the claims of the '427 patent under 35 U.S.C. § 271(e)(2)(A).

81. Upon FDA approval of ANDA No. 20-0899, Banner will further infringe the '427 Patent by making, using, offering to sell, and selling generic dutasteride capsules in the United States and/or importing such tablets into the United States, and by actively inducing and

contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

82. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Banner will actively encourage and/or instruct others on how to use its proposed generic dutasteride capsules in a way that infringes at least one claim of the '427 Patent. Upon information and belief, Banner will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '427 Patent.

83. Upon information and belief, Banner had actual and constructive knowledge of the '427 Patent prior to filing ANDA No. 20-0899 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '427 Patent.

84. If Banner's infringement of the '427 patent is not enjoined, GSK will suffer substantial and irreparable harm for which there is no remedy at law.

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

85. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-84 of this Complaint.

86. Anchen's submission of ANDA No. 20-2530 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic dutasteride capsules before the expiration of the '467 Patent constitutes infringement of one or more of the claims of the '467 patent under 35 U.S.C. § 271(e)(2)(A).

87. Upon FDA approval of ANDA No. 20-2530, Anchen will further infringe the '467 Patent by making, using, offering to sell, and selling generic dutasteride capsules in the United States and/or importing such tablets into the United States, and by actively inducing and

contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

88. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Anchen will actively encourage and/or instruct others on how to use its proposed generic dutasteride capsules in a way that infringes at least one claim of the '467 Patent. Upon information and belief, Anchen will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '467 Patent.

89. Upon information and belief, Anchen had actual and constructive knowledge of the '467 Patent prior to filing ANDA No. 20-2530 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '467 Patent.

90. If Anchen's infringement of the '467 patent is not enjoined, GSK will suffer substantial and irreparable harm for which there is no remedy at law.

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

91. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-90 of this Complaint.

92. Anchen's submission of ANDA No. 20-2509 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic dutasteride and tamsulosin capsules before the expiration of the '467 Patent constitutes infringement of one or more of the claims of the '467 patent under 35 U.S.C. § 271(e)(2)(A).

93. Upon FDA approval of ANDA No. 20-2509, Anchen will further infringe the '467 Patent by making, using, offering to sell, and selling generic dutasteride and tamsulosin capsules in the United States and/or importing such tablets into the United States, and by actively

inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by the Court.

94. Upon information and belief, by selling and offering for sale its proposed generic dutasteride and tamsulosin capsules, Anchen will actively encourage and/or instruct others on how to use its proposed generic dutasteride and tamsulosin capsules in a way that infringes at least one claim of the '467 Patent. Upon information and belief, Anchen will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '467 Patent.

95. Upon information and belief, Anchen had actual and constructive knowledge of the '467 Patent prior to filing ANDA No. 20-2509 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '467 Patent.

96. If Anchen's infringement of the '467 patent is not enjoined, GSK will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A judgment that Banner has infringed each of the Patents-in-Suit;

B. A judgment that Anchen has infringed the '467 Patent;

C. An order restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of generic dutasteride capsules, as claimed in the Patents-in-Suit;

D. An order restraining and enjoining Anchen, its officers, agents, attorneys and employees, and those acting in privity or concert with Anchen, from engaging in the

commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of generic dutasteride and tamsulosin capsules, as claimed in the '467 Patent;

E. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the aforementioned ANDA No. 20-0899 for Banner's proposed generic dutasteride capsules shall not be earlier than the expiration date of the Patents-in-Suit;

F. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the aforementioned ANDA No. 20-2530 for Anchen's proposed generic dutasteride capsules shall not be earlier than the expiration date of the '467 Patent;

G. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the aforementioned ANDA No. 20-2509 for Anchen's proposed generic dutasteride and tamsulosin capsules shall not be earlier than the expiration date of the '467 Patent;

H. Damages or other monetary relief to GSK if Banner and/or Anchen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of generic dutasteride capsules before the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which GSK is or becomes entitled;

I. Damages or other monetary relief to GSK if Anchen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of generic dutasteride and tamsulosin capsules before the latest expiration date of the '467 Patent, including any extensions and/or additional periods of exclusivity to which GSK is or becomes entitled;

J. Costs and reasonable attorneys' fees of this action pursuant to 35 U.S.C. §§ 271(e)(4) and 285; and

K. Other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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