IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC (f/k/a SMITHKLINE BEECHAM CORPORATION),	)	
Plaintiff,	)	
v.	)	C.A. No. _____
MYLAN, INC., MYLAN PHARMACEUTICALS, INC., and IMPAX LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff GlaxoSmithKline LLC (formerly known as SmithKline Beecham Corporation) ("Plaintiff" or "GSK"), for its Complaint against Defendants Mylan, Inc. ("Mylan Inc."), Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals," together with Mylan Inc., "Mylan"), and Impax Laboratories, Inc. ("Impax") (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 two Abbreviated New Drug Applications ("ANDA") filed with the U.S. Food and Drug Administration ("FDA"):

- ANDA No. 203241 filed by Mylan for approval to market 0.5 mg dutasteride capsules, a proposed generic version of GSK's AVODART® drug product.

- ANDA No. 203105 filed by Impax for approval to market 0.5 mg/0.4 mg dutasteride and tamsulosin hydrochloride 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 Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Upon information and belief, Mylan Inc. develops, manufactures, and sells generic pharmaceutical products for the United States market through various directly- or indirectly-owned operating subsidiaries, including its wholly owned-subsidiary, Mylan Pharmaceuticals.

5. Upon information and belief, Defendant Mylan Pharmaceuticals is a corporation organized and existing under the laws of the State of West Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Inc. established Mylan Pharmaceuticals, its wholly-owned subsidiary, for the purposes of distributing, marketing, offering for sale and selling its generic drugs throughout the United States. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals work in concert with one another, and with other Mylan subsidiaries, to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district. Upon information and belief, Mylan Inc. directs the operations, management and activities of Mylan Pharmaceuticals in the United States.

6. Upon information and belief, following any FDA approval of ANDA No. 203241, Mylan Inc. and Mylan Pharmaceuticals will work in concert, and with other Mylan subsidiaries, to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 203241 throughout the United States, and/or import such generic products into the United States.

7. Upon information and belief, Defendant Impax is a corporation organized and existing under the laws of Delaware with its principal place of business at 30831 Huntwood Avenue, Hayward, California, 94544.

8. Upon information and belief, following any FDA approval of ANDA No. 203105, Impax will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 203105 throughout the United States, and/or import such generic products into the United States.

JURISDICTION AND VENUE

9. 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 and 1400.

10. This Court has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals because, *inter alia*, they have each committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement in filing ANDA No. 203241 that has led to foreseeable harm and injury to GSK, a Delaware corporation.

11. This Court also has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals because, *inter alia*, they have purposely availed themselves of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware such that they should reasonably anticipate being hauled into court here. On information and belief, Mylan Inc. and Mylan Pharmaceuticals have persistent, systematic and continuous contacts with Delaware as set forth below.

12. Upon information and belief, Mylan Pharmaceuticals is registered to conduct business in the State of Delaware, and has appointed a registered agent for such purposes. Mylan Pharmaceuticals is therefore subject to general jurisdiction in the State of Delaware.

13. Upon information and belief, Mylan Inc. maintains a website, www.mylan.com, advertising Mylan Inc.'s "global reach." According to Mylan Inc.'s website, Mylan Inc. is "one of the world's leading generics and specialty pharmaceutical companies, providing products to customers in more than 150 countries and territories," and "[t]he second largest generic pharmaceutical company in the U.S. by sales volume."

14. Upon information and belief, Mylan Pharmaceuticals distributes for sale hundreds of drug products through the United States, including in this judicial district. Upon information and belief, Mylan Pharmaceuticals maintains a website, www.mylanpharms.com, advertising the drug products it manufactures and/or sells in the United States. According to Mylan Pharmaceuticals' website, Mylan Pharmaceuticals "has one of the largest product portfolios in the U.S., consisting of more than 200 products."

15. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals regularly do business in Delaware and have engaged in a persistent course of conduct within

Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have done so with each other's authorization, participation, and assistance, or acting in concert with each other.

16. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals operate as an integrated, unitary generic pharmaceutical business. For example, Mylan Inc. includes within its Annual Report the activities of its wholly-owned subsidiary Mylan Pharmaceuticals, including the revenues earned. The Mylan Inc. website, appearing at www.mylan.com, provides information about both Mylan Inc. and Mylan Pharmaceuticals. Mylan Inc. is divided into several business units, including the "Generics" business. Upon information and belief, Mylan Pharmaceuticals, in whole or in part, comprises this "Generics" business, particularly within the United States.

17. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within Delaware.

18. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have previously availed themselves of the rights and privileges of this forum for the purpose of litigating patent disputes. For example, Mylan Inc. and Mylan Pharmaceuticals sought a declaratory judgment of noninfringement, unenforceability, and/or invalidity in *Mylan Pharmaceuticals Inc. v. Eurand, Inc.*, No. 10-306-SLR (D. Del.). Mylan Inc. and Mylan Pharmaceuticals have also submitted to this Court's jurisdiction by asserting counterclaims in other civil actions in this jurisdiction. Specifically, Mylan Inc. and Mylan Pharmaceuticals

admitted jurisdiction for the purpose of the litigation and filed counterclaims in *Somaxon Pharmaceuticals, Inc. et al v. Actavis Elizabeth LLC et al*, 1:10-cv-01100 (SLR), which is pending in this District.

19. Upon information and belief, Mylan Inc. participated in, contributed to, aided, abetted and/or induced the submission to the U.S. Food and Drug Administration ("FDA") of ANDA No. 203241.

20. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals will manufacture, market, and/or sell within the United States the generic 0.5 mg dutasteride capsules described in ANDA No. 203241 if FDA approval is granted. If ANDA No. 203241 is approved, the generic 0.5 mg dutasteride capsules charged with infringing the Patents-in-Suit, would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

21. This Court has personal jurisdiction over Impax because, *inter alia*, it is a Delaware corporation.

AVODART®

22. 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 approved for the treatment of symptomatic benign prostatic hyperplasia ("BPH")—essentially, enlargement of the prostate gland.

23. 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.

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

JALYN™

25. GSK holds approved New Drug Application ("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 approved for the treatment of symptomatic BPH.

26. 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

27. GSK is the owner of the '467 Patent, entitled "Androstenone Derivative," which was duly and legally issued on October 15, 1996. A true and complete copy of the '467 Patent is attached hereto as **Exhibit A**.

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

29. 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.

30. GSK is the owner of the '976 Patent, entitled "Androstenone Derivative," which was duly and legally issued on December 8, 1998. A true and complete copy of the '976 Patent is attached hereto as **Exhibit B**.

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

32. 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.

33. GSK is the owner of the '427 Patent, entitled "Androstenones," which was duly and legally issued on December 7, 1999. A true and complete copy of the '427 Patent is attached hereto as **Exhibit C**.

34. The '427 Patent, *inter alia*, 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.

35. 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 MYLAN

36. By letter dated August 2, 2011 ("the Mylan Notice Letter"), Mylan notified GSK that it had submitted ANDA No. 203241 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, Mylan intends to engage in commercial manufacture, use, and sale of generic 0.5 mg dutasteride capsules promptly upon receiving FDA approval to do so.

37. By filing ANDA No. 203241, Mylan has necessarily represented to the FDA that its proposed generic 0.5 mg dutasteride capsules have the same active ingredients as

AVODART®, have the same route of administration, dosage form, and strength as AVODART®, and are bioequivalent to AVODART®.

38. In the Mylan Notice Letter, Mylan notified GSK that its ANDA contained a "Paragraph IV certification" asserting that, in Mylan'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 Mylan's proposed generic 0.5 mg dutasteride capsules.

39. Mylan has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 203241 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 term of the Patents-in-Suit.

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

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

42. GSK is entitled under 35 U.S.C. § 271(e)(4) to full relief from Mylan's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 203241 relating to Mylan's proposed generic dutasteride capsules shall not be earlier than the expiration of Patents-in-Suit.

INFRINGEMENT BY IMPAX

43. By letter dated August 17, 2011 ("the Impax Notice Letter"), Impax notified GSK that it had submitted ANDA No. 203105 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 hydrochloride capsules before the expiration of the Patents-in-Suit. Upon information and belief, Impax intends to engage in commercial manufacture, use, and sale of generic 0.5 mg/0.4 mg dutasteride and tamsulosin hydrochloride capsules promptly upon receiving FDA approval to do so.

44. By filing ANDA No. 203105, Impax has necessarily represented to the FDA that the components of its proposed generic 0.5 mg/0.4 mg dutasteride and tamsulosin hydrochloride capsules have the same active ingredients as JALYN™, have the same route of administration, dosage form, and strength as JALYN™, and are bioequivalent to JALYN™.

45. In the Impax Notice Letter, Impax notified GSK that its ANDA contained a "Paragraph IV certification" asserting that, in Impax'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 Impax's proposed generic 0.5 mg/0.4 mg dutasteride and tamsulosin hydrochloride capsules.

46. Impax has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 203105 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of generic dutasteride and tamsulosin hydrochloride capsules before the expiration of the term of the Patents-in-Suit.

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

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

49. GSK is entitled under 35 U.S.C. § 271(e)(4) to full relief from Impax's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 203105 relating to Impax's proposed generic dutasteride and tamsulosin hydrochloride capsules shall not be earlier than the expiration of the Patents-in-Suit.

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

50. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-49 of this Complaint.

51. Mylan's submission of ANDA No. 203241 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic dutasteride capsules before the expiration of the Patents-In-Suit constitutes infringement of one or more of the claims of the '467 Patent under 35 U.S.C. § 271(e)(2)(A).

52. Upon FDA approval of ANDA No. 203241, Mylan 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.

53. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Mylan 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, Mylan knows, will know, or should know, that its

encouragement and/or instructions will result in infringement of at least one claim of the '467 Patent.

54. Upon information and belief, Mylan had actual and constructive knowledge of the '467 Patent prior to filing ANDA No. 203241 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '467 Patent.

55. If Mylan'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 (Mylan)

56. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-55 of this Complaint.

57. Mylan's submission of ANDA No. 203241 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).

58. Upon FDA approval of ANDA No. 203241, Mylan 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.

59. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Mylan 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, Mylan, will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '976 Patent.

60. Upon information and belief, Mylan had actual and constructive knowledge of the '976 Patent prior to filing ANDA No. 203241 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '976 Patent.

61. If Mylan'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 (Mylan)

62. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-61 of this Complaint.

63. Mylan's submission of ANDA No. 203241 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).

64. Upon FDA approval of ANDA No. 203241, Mylan 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.

65. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Mylan 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, Mylan knows, will know, or should know, that its

encouragement and/or instructions will result in infringement of at least one claim of the '427 Patent.

66. Upon information and belief, Mylan had actual and constructive knowledge of the '427 Patent prior to filing ANDA No. 203241 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '427 Patent.

67. If Mylan'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 (Impax)

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

69. Impax's submission of ANDA No. 203105 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic dutasteride and tamsulosin hydrochloride 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).

70. Upon FDA approval of ANDA No. 203105, Impax will further infringe the '467 Patent by making, using, offering to sell, and selling generic dutasteride and tamsulosin hydrochloride capsules in the United States and/or importing such capsules 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.

71. Upon information and belief, by selling and offering for sale its proposed generic dutasteride and tamsulosin hydrochloride capsules, Impax will actively encourage and/or instruct others on how to use its proposed generic dutasteride and tamsulosin hydrochloride capsules in a way that infringes at least one claim of the '467 Patent. Upon information and

belief, Impax knows, will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '467 Patent.

72. Upon information and belief, Impax had actual and constructive knowledge of the '467 Patent prior to filing ANDA No. 203105 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '467 Patent.

73. If Impax'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 '976 PATENT (Impax)

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

75. Impax's submission of ANDA No. 203105 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic dutasteride and tamsulosin hydrocholoride 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).

76. Upon FDA approval of ANDA No. 203105, Impax will further infringe the '976 Patent by making, using, offering to sell, and selling generic dutasteride and tamsulosin hydrochloride 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.

77. Upon information and belief, by selling and offering for sale its proposed generic dutasteride and tamsulosin hydrochloride capsules, Impax will actively encourage and/or instruct others on how to use its proposed generic dutasteride and tamsulosin hydrochloride capsules in a way that infringes at least one claim of the '976 Patent. Upon information and

belief, Impax knows, will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '976 Patent.

78. Upon information and belief, Impax had actual and constructive knowledge of the '976 Patent prior to filing ANDA No. 203105 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '976 Patent.

79. If Impax'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 SIX: INFRINGEMENT OF THE '427 PATENT (Impax)

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

81. Impax's submission of ANDA No. 203105 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic dutasteride and tamsulosin hydrochloride 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).

82. Upon FDA approval of ANDA No. 203105, Impax will further infringe the '427 Patent by making, using, offering to sell, and selling generic dutasteride and tamsulosin hydrochloride 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.

83. Upon information and belief, by selling and offering for sale its proposed generic dutasteride and tamsulosin hydrochloride capsules, Impax will actively encourage and/or instruct others on how to use its proposed generic dutasteride and tamsulosin hydrochloride capsules in a way that infringes at least one claim of the '427 Patent. Upon information and

belief, Impax knows, will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '427 Patent.

84. Upon information and belief, Impax had actual and constructive knowledge of the '427 Patent prior to filing ANDA No. 203105 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '427 Patent.

85. If Impax's infringement of the '427 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 Mylan has infringed each of the Patents-in-Suit;

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

C. An order restraining and enjoining Mylan, its officers, agents, attorneys and employees, and those acting in privity or concert with Mylan, 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, until after 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;

D. An order restraining and enjoining Impax, its officers, agents, attorneys and employees, and those acting in privity or concert with Impax, 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 hydrochloride capsules, until after 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;

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. 203241 for Mylan's proposed generic dutasteride capsules shall not be earlier than the latest 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. 203105 for Impax's proposed generic dutasteride and tamsulosin hydrochloride capsules shall not be earlier than the latest expiration date of the Patents-in-Suit;

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

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

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

OF COUNSEL:

William F. Lee
Lisa J. Pirozzolo
WILMERHALE LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Christopher R. Noyes
WILMERHALE LLP
399 Park Avenue
New York, NY 10022
(212) 230-8800

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MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
dfahenstock@mnat.com

Attorneys for Plaintiff GlaxoSmithKline LLC (f/k/a SmithKline Beecham Corporation)