IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
BARR PHARMACEUTICALS, INC. and BARR LABORATORIES, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("Plaintiff" or "GSK"), for its complaint herein against Defendants Barr Pharmaceuticals, Inc. ("Barr Pharm") and Barr Laboratories, Inc. ("Barr Labs") (collectively, "Defendants" or "Barr"), upon personal knowledge as to its own actions and upon information and belief as to the actions of others, alleges as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

PARTIES

2. Plaintiff GSK is a corporation organized and existing under the laws of Pennsylvania and having an office and place of business at One Franklin Plaza, Philadelphia, PA 19102. GSK is a research-based pharmaceutical company.

3. Upon information and belief, Defendant Barr Pharm is a corporation organized and existing under the laws of Delaware and having a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

4. Upon information and belief, Defendant Barr Labs is a corporation organized and existing under the laws of Delaware and having a principal place of business at 223 Quaker Road, P.O. Box 2900, Pomona, NY 10970, and with executive offices at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

5. Barr Pharm and Barr Labs are referred to hereinafter collectively as "Barr."

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Defendants because both Barr Pharm and Barr Labs are incorporated in Delaware.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(c) and 28 U.S.C. § 1400(b).

AVODART

9. 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.

10. Pursuant to 21 U.S.C. § 355(b)(1) and attendant United States Food and Drug Administration ("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: United States Patent No. 5,565,467 (the "'467 Patent"); United

States Patent No. 5,846,976 (the "'976 Patent"); and United States Patent No. 5,998,427 (the "'427 Patent").

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

THE PATENTS-IN-SUIT

12. 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.

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

14. The exclusivity afforded by the '467 Patent expires on November 20, 2015.

15. 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.

16. 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.

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

18. The exclusivity afforded by the '976 Patent expires on September 17, 2013.

19. 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.

20. 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.

21. 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.

22. The exclusivity afforded by the '427 Patent expires on September 17, 2013.

23. 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.

BARR'S ANDA

24. Upon information and belief, Barr Labs submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 90-095 pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of generic 0.5 mg dutasteride capsules before the expiration of the Patents-in-Suit.

25. In a January 11, 2008 letter notifying GSK of its ANDA filing, Barr Labs informed GSK that:

> "[T]he product that is the subject of Barr's ANDA No. 90-095 ("Barr's ANDA Product") is a generic version of Avodart. Barr's ANDA product is a 0.5 mg dutasteride capsule. The active ingredient in Barr's ANDA product is dutasteride. Barr's ANDA product will be marketed for the currently approved indication for Avodart."

26. Upon information and belief, Barr Labs has made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the Patents-in-Suit are invalid, unenforceable and/or will not be infringed by Defendants' manufacture, use and/or sale of generic dutasteride capsules (the "Paragraph IV Certification").

27. Defendants have committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 90-095 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.

28. The commercial manufacture, use, offer for sale, sale and/or importation of the generic dutasteride capsules for which Defendants seek approval in their ANDA will directly infringe one or more claims of the Patents-in-Suit.

29. The sale or offer for sale of the generic dutasteride capsules for which Defendants seek approval in their ANDA also will actively induce infringement and contributorily infringe one or more claims of the Patents-in-Suit.

30. GSK is entitled under 35 U.S.C. § 271(e)(4) to full relief from Defendants' acts of infringement, including an Order by this Court ensuring that the effective date of any approval of the aforementioned ANDA, No. 90-095, relating to Defendants' generic dutasteride capsules shall not be earlier than the expiration of the exclusivity afforded the Patents-in-Suit.

31. Defendants were aware of each of the Patents-in-Suit when Barr Labs filed its ANDA, and was aware that the filing of the ANDA with a request for its approval prior to the September 17, 2013 expiration date of the '976 and '427 Patents, and/or prior to the

November 20, 2015 expiration date of the '467 Patent, was an act of infringement of those patents.

COUNT ONE: INFRINGEMENT OF THE '467 PATENT

32. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-31 of this Complaint.

33. Barr has infringed, induced the infringement of, and contributed to the infringement of the '467 Patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 90-095, which includes the Paragraph IV Certification as to the '467 Patent and which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale and/or importation of generic dutasteride capsules for the treatment of BPH prior to the expiration of the '467 Patent.

34. Barr has knowingly infringed the '467 Patent.

35. GSK will be irreparably harmed if Barr is not enjoined from infringing the '467 Patent.

COUNT TWO: INFRINGEMENT OF THE '976 PATENT

36. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-31 of this Complaint.

37. Barr has infringed, induced the infringement of, and contributed to the infringement of the '976 Patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 90-095, which includes the Paragraph IV Certification as to the '976 Patent and which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale and/or importation of generic dutasteride capsules for the treatment of BPH prior to the expiration of the '976 Patent.

38. Barr has knowingly infringed the '976 Patent.

39. GSK will be irreparably harmed if Barr is not enjoined from infringing the '976 Patent.

COUNT THREE: INFRINGEMENT OF THE '427 PATENT

40. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-31 of this Complaint.

41. Barr has infringed, induced the infringement of, and contributed to the infringement of the '427 Patent pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 90-095, which includes the Paragraph IV Certification as to the '427 Patent and which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale and/or importation of generic dutasteride capsules for the treatment of BPH prior to the expiration of the '427 Patent.

42. Barr has knowingly infringed the '427 Patent.

43. GSK will be irreparably harmed if Barr is not enjoined from infringing the '427 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A judgment that Defendants have infringed each of the Patents-in-Suit;

B. 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;

C. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the aforementioned ANDA, No. 90-095, for Defendants' generic dutasteride capsules shall not be earlier than the expiration date of the Patents-in-Suit;

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

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

February 25, 2008.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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