IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE LLC (f/k/a SMITHKLINE BEECHAM CORPORATION),	)	
Plaintiff,	)	
v.	)	C.A. No. _____
ROXANE LABORATORIES, INC., WATSON PHARMA, INC., WATSON PHARMACEUTICALS, INC., and WATSON LABORATORIES, INC. – FLORIDA,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff GlaxoSmithKline LLC (formerly known as SmithKline Beecham Corporation) ("Plaintiff" or "GSK"), for its Complaint against Defendants Roxane Laboratories, Inc. ("Roxane"), Watson Pharma, Inc. ("Watson Pharma"), Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals"), and Watson Laboratories, Inc. – Florida ("Watson Laboratories," together with Watson Laboratories and Watson Pharmaceuticals, "Watson") (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. 202204 filed by Roxane for approval to market 0.5 mg dutasteride capsules, a proposed generic version of GSK's AVODART® drug product.
- ANDA No. 202808 filed by Watson for approval to market 0.5 mg dutasteride capsules, a proposed generic version of GSK's AVODART® 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 Roxane is a corporation organized under the laws of Nevada, with a principal place of business at 1809 Wilson Road, Columbus, Ohio 43228.

5. Upon information and belief, following any FDA approval of ANDA No. 202204, Roxane will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 202204 throughout the United States, and/or import such generic products into the United States.

6. Upon information and belief, Defendant Watson Pharma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962. Upon information and belief, Watson Pharma distributes pharmaceutical products throughout the United States including in this judicial district and is the distributor of drugs that Watson Laboratories manufactures or for which Watson Laboratories is the named applicant on approved ANDAs. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals.

7. Upon information and belief, Defendant Watson Pharmaceuticals is a Nevada corporation, having a principal place of business at 311 Bonnie Circle, Corona, California 92880

and 360 Mount Kemble Avenue, Morristown, New Jersey 07962. Upon information and belief, Watson Pharmaceuticals develops, manufactures, and sells generic pharmaceutical products for the United States market through various directly- or indirectly-owned operating subsidiaries, including Watson Laboratories and Watson Pharma.

8. Upon information and belief, Defendant Watson Laboratories is a corporation organized under the laws of Florida, with a principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Laboratories was formerly known as Andrx Pharmaceuticals, Inc., and is a wholly-owned subsidiary of Andrx Corp., a Delaware corporation that is wholly-owned by Watson Pharmaceuticals, Inc. Upon information and belief, Defendant Watson Laboratories develops and manufactures generic pharmaceutical products for the United States market.

9. Upon information and belief, Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories work in concert, and with other Watson subsidiaries, to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district.

10. Upon information and belief, following any FDA approval of ANDA No. 202808, Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories will work in concert, and with other Watson subsidiaries, to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 202808 throughout the United States, and/or import such generic products into the United States.

JURISDICTION AND VENUE

11. 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 1400(b).

12. This Court has personal jurisdiction over Roxane because, *inter alia*, it has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement in filing ANDA No. 202204 that has led to foreseeable harm and injury to GSK, a Delaware corporation.

13. This Court has personal jurisdiction over Roxane because, *inter alia*, Roxane has purposely availed itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware such that it should reasonably anticipate being hauled into court here. On information and belief, Roxane has persistent, systematic and continuous contacts with Delaware.

14. Upon information and belief, Roxane regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware. Upon information and belief, Roxane derives substantial revenue from Delaware drug sales and has availed itself of the privilege of conducting business within the State of Delaware.

15. In addition, upon information and belief, Roxane has previously availed itself of this forum for the purpose of litigating patent disputes. For example, on March 1, 2011, Roxane filed a counterclaim seeking a declaratory judgment of noninfringement in *Abbott Laboratories v. Roxane Laboratories, Inc.*, No. 10-998-GMS (D. Del.).

16. This Court has personal jurisdiction over Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories 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. 202808 that has led to foreseeable harm and injury to GSK, a Delaware corporation.

17. This Court also has personal jurisdiction over Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories because, *inter alia*, they have purposely availed themselves of the benefits and protections of the laws of Delaware such that they should reasonably anticipate being hauled into court here. On information and belief, Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories have had persistent, systematic and continuous contacts with Delaware.

18. Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories directly or through an agent, including each other, regularly do or solicit business in Delaware, engage in persistent courses of conduct in Delaware, and/or derive substantial revenue from the development, manufacture and/or sale of pharmaceutical products that are sold in Delaware.

19. Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories are agents of each other and/or work in concert with each other and/or other direct and indirect subsidiaries of Watson Pharmaceuticals with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products throughout the United States, including in Delaware.

20. Upon information and belief, Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories share common employees, officers, and directors, as well as common facilities.

21. Upon information and belief, Watson Pharmaceuticals organizes its operations by division—Global Generics, Global Brands, and Anda Distribution—rather than by subsidiary, and reports its financial results to investors by reference to its divisions, not to its subsidiaries.

22. Upon information and belief, the Global Generics division, which is responsible for developing and submitting ANDAs, as well as manufacturing and marketing generic pharmaceuticals, relies on the concerted efforts of Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories.

23. Upon information and belief, Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories are agents of each other and/or operate in concert as integrated parts of Watson's Global Generics division.

24. Upon information and belief, Watson Pharmaceuticals consolidates its financial results and does not provide separate financial reports for each Watson subsidiary. For example, Watson Pharmaceuticals consolidated and reported its financial results with Watson Laboratories and Watson Pharma in its December 31, 2010, 10-K filing.

25. Upon information and belief, neither Watson Pharma nor Watson Laboratories maintains an independent website; instead, Watson Pharmaceuticals maintains a single website for all Watson entities.

26. Watson Pharmaceuticals displays on its website Watson Pharma's "Terms and Conditions of Sale." Watson Pharma's address is listed as 311 Bonnie Circle, Corona, CA 92880, the principal place of business for Watson Pharmaceuticals. Watson Pharmaceuticals also displays on its website a "Return Goods Policy" for Watson Pharma that applies to all brand, generic, and diagnostic products.

27. Upon information and belief, Watson Pharmaceuticals and Watson Pharma participated in, contributed to, aided, abetted and/or induced the submission to the U.S. Food and Drug Administration ("FDA") of ANDA No. 202808. For instance, by letter dated May 16, 2011, Watson Laboratories directed GSK to send any correspondence or requests for confidential

access concerning ANDA No. 202808 to its Watson Laboratories "in-house counsel," Mr. G. Michael Bryner, who is registered with the U.S. Patent and Trademark Office as an attorney employed by Watson Pharmaceuticals.

28. Watson Pharmaceuticals' website states that its Global Generics division has a U.S. portfolio of more than 160 pharmaceutical products (including products for which Watson Laboratories is the named ANDA applicant); that it filed 34 new ANDAs in 2010; and that it has more than 145 product applications pending outside the United States.

29. Upon information and belief, Watson Laboratories is the named applicant on ANDAs for numerous generic drugs, including many that are actively manufactured, sold and used in Delaware and elsewhere in the United States.

30. Upon information and belief, Watson Pharma, a Delaware corporation, is the distributor of drugs for which Watson Laboratories is the named applicant in the FDA's Approved Drug Product List. Upon information and belief, Watson Pharma, acting as the agent of Watson Laboratories and Watson Pharmaceuticals, markets and sells Watson's drug products in Delaware and elsewhere in the United States.

31. Upon information and belief, Watson Pharma is a Delaware corporation that distributes and sells in the United States certain generic pharmaceutical products that are manufactured by Watson Laboratories and for which Watson Laboratories is the named ANDA applicant and has received FDA approval.

32. Upon information and belief, Watson Pharma is licensed to do business in Delaware and maintains at least active "Pharmacy CSR" and "Distributor/Manufacturer CSR" licenses in Delaware. On its licenses, Watson Pharma regularly lists its mailing address as Corona, CA 92880, the principal place of business for Watson Pharmaceuticals. Other Watson

entities with various mailing addresses also have pharmacy-related licenses to do business in Delaware.

33. Upon information and belief, various drugs for which Watson Laboratories is the named ANDA applicant are distributed by Watson Pharma and are available at retail pharmacies in Delaware including Walgreens/Happy Harry's, Rite Aid, and CVS.

34. Upon information and belief, Watson Pharma and Watson Laboratories are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. Upon information and belief, such agreements are not arm's length.

35. Upon information and belief, Watson Pharmaceuticals and/or Watson Laboratories earn revenue from the distribution in Delaware by Watson Pharma of generic pharmaceutical products that are manufactured by Watson Laboratories or for which Watson Laboratories is the named applicant on approved ANDAs.

36. Watson Pharmaceuticals' website provides links to its distribution network where physicians, pharmacies, and distributors in Delaware and elsewhere are able to directly order Watson's products, including products manufactured by Watson Laboratories and products for which Watson Laboratories is the named ANDA applicant, via Watson Pharmaceuticals' internet distribution network.

37. Watson Pharmaceuticals' website also provides links to its VIPConnect™, VIPpharm™, and VIPCSOS.com™ product-ordering systems. Upon information and belief, physicians and pharmacies located in Delaware directly order Watson's products, including products manufactured by Watson Laboratories and products for which Watson Laboratories is the named ANDA applicant, through the VIP ordering systems accessible via Watson Pharmaceuticals' website.

38. Upon information and belief, Watson Pharma, Watson Pharmaceuticals, and Watson Laboratories will manufacture, market, and/or sell within the United States the generic 0.5 mg dutasteride capsules described in Watson's ANDA No. 202808 if FDA approval is granted. If ANDA No. 202808 is approved, the generic 0.5 mg dutasteride capsules charged with infringing the '467 Patent, 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 person in Delaware, all of which would have a substantial effect on Delaware.

39. This Court has personal jurisdiction over Watson Pharma by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

40. This Court has personal jurisdiction over Watson Pharmaceuticals by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

41. This Court has personal jurisdiction over Watson Laboratories by virtue of, *inter alia*, its systematic and continuous contacts with Delaware.

42. Upon information and belief, Watson Laboratories has purposely availed itself of Delaware courts by, *inter alia*:

a. joining as plaintiff with other parties filing a complaint for patent infringement in the District of Delaware on January 15, 2009 against Lupin Ltd. and Lupin Pharmaceuticals, Inc., *Sciele Pharma, Inc. v. Lupin Ltd.*, Civil Action No. 1:09-cv-00037-JJF (D. Del.);

b. joining as a plaintiff with other parties, including other Watson parties, filing a complaint for patent infringement in the District of Delaware on February 18, 2010

against Mylan Inc. and Mylan Pharmaceuticals, Inc., *Shionogi Pharma, Inc. v. Mylan Inc.*, Civil Action No. 1:10-cv-00135-RBK (D. Del.);

c. filing counterclaims in the District of Delaware on February 18, 2010 in *Allergan, Inc. v. Watson Pharms., Inc.*, Civil Action No. 1:09-cv-00511-GMS (D. Del.), and *Takeda Pharm. Co. v. Watson Labs., Inc.*, Civil Action No. 1:09-cv-00917-SLR (D. Del.);

d. filing counterclaims in the District of Delaware on May 25, 2010 in *Abbott Laboratories & Abbott Respiratory LLC v. Watson Laboratories, Inc. – Florida*, Civil Action No. 1:10-cv-00373-SLR (D. Del.); and

e. filing counterclaims in the District of Delaware on May 6, 2011, in *Abbott Laboratories v. Watson Laboratories, Inc. - Florida*, No. 11-251-SLR (D. Del.).

AVODART®

43. 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.

44. 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.

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

THE PATENTS-IN-SUIT

46. 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**.

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

48. 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.

49. 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**.

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

51. 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.

52. 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**.

53. 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.

54. 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 ROXANE

55. By letter dated May 4, 2011 ("the Roxane Notice Letter"), Roxane notified GSK that it had submitted ANDA No. 202204 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, Roxane intends to engage in commercial manufacture, use, and sale of generic 0.5 mg dutasteride capsules promptly upon receiving FDA approval to do so.

56. By filing ANDA No. 202204, Roxane 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®.

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

58. Roxane has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 202204 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.

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

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

61. GSK is entitled under 35 U.S.C. § 271(e)(4) to full relief from Roxane's acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 202204 relating to Roxane's proposed generic dutasteride capsules shall not be earlier than the expiration of the Patents-in-Suit.

INFRINGEMENT BY WATSON

62. By letter dated May 16, 2011 ("the Watson Notice Letter"), Watson notified GSK that it had submitted ANDA No. 202808 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, Watson intends to engage in commercial manufacture, use, and sale of generic 0.5 mg dutasteride capsules promptly upon receiving FDA approval to do so.

63. By filing ANDA No. 202808, Watson 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®.

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

65. Watson has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 202808 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 ’467 Patent.

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

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

68. GSK is entitled under 35 U.S.C. § 271(e)(4) to full relief from Watson’s acts of infringement, including an Order by this Court ensuring that the effective date of any approval of ANDA No. 202808 relating to Watson’s proposed generic dutasteride capsules shall not be earlier than the expiration of the ‘467 Patent.

COUNT ONE: INFRINGEMENT OF THE ’467 PATENT (Roxane)

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

70. Roxane’s submission of ANDA No. 202204 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).

71. Upon FDA approval of ANDA No. 202204, Roxane 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.

72. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Roxane 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, Roxane 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.

73. Upon information and belief, Roxane had actual and constructive knowledge of the '467 Patent prior to filing ANDA No. 202204 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '467 Patent.

74. If Roxane'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 (Roxane)

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

76. Roxane's submission of ANDA No. 202204 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).

77. Upon FDA approval of ANDA No. 202204, Roxane 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.

78. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Roxane 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, Roxane 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.

79. Upon information and belief, Roxane had actual and constructive knowledge of the '976 Patent prior to filing ANDA No. 202204 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '976 Patent.

80. If Roxane'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 (Roxane)

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

82. Roxane's submission of ANDA No. 202204 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).

83. Upon FDA approval of ANDA No. 202204, Roxane 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.

84. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Roxane 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, Roxane 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.

85. Upon information and belief, Roxane had actual and constructive knowledge of the '427 Patent prior to filing ANDA No. 202204 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '427 Patent.

86. If Roxane'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 (Watson)

87. GSK hereby realleges and incorporates by reference the allegations of paragraphs 1-86 of this Complaint.

88. Watson's submission of ANDA No. 202808 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).

89. Upon FDA approval of ANDA No. 202808, Watson 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.

90. Upon information and belief, by selling and offering for sale its proposed generic dutasteride capsules, Watson 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, Watson 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.

91. Upon information and belief, Watson had actual and constructive knowledge of the '467 Patent prior to filing ANDA No. 202808 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '467 Patent.

92. If Watson'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 Roxane has infringed each of the Patents-in-Suit;

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

C. An order restraining and enjoining Roxane, its officers, agents, attorneys and employees, and those acting in privity or concert with Roxane, 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 Watson, its officers, agents, attorneys and employees, and those acting in privity or concert with Watson, 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 expiration date of the '467 Patent, 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. 202204 for Roxane's proposed generic dutasteride capsules shall not be earlier than the expiration dates 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. 202808 for Watson's proposed generic dutasteride capsules shall not be earlier than the expiration date of the '467 Patent;

G. Damages or other monetary relief to GSK if Roxane and/or Watson 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 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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June 17, 2011