IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WATSON LABORATORIES, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	**Civil Action No. _____**
	§	
BARR LABORATORIES, INC. and BARR PHARMACEUTICALS, INC.	§	
	§	
Defendants.	§	
	§	

COMPLAINT

Plaintiff Watson Laboratories, Inc. (hereinafter "Watson"), by its undersigned attorneys, for its Complaint against defendants Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. (hereinafter collectively "Barr") herein, alleges as follows:

THE PARTIES

1. Plaintiff Watson is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 577 Chipeta Way, Salt Lake City, Utah 84108.

2. Upon information and belief, defendant Barr Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

3. Upon information and belief, defendant Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 225 Summit Avenue, Montvale, New Jersey 07645.

NATURE OF THE ACTION

4. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Letters Patent Nos. 5,601,839 ("the '839 patent"; Exhibit A hereto); 5,834,010 ("the '010 patent"; Exhibit B hereto); 6,743,441 ("the '441 patent"; Exhibit C hereto); 7,081,249 ("the '249 patent"; Exhibit D hereto); 7,081,250 ("the '250 patent"; Exhibit E hereto); 7,081,251 ("the '251 patent"; Exhibit F hereto); 7,081,252 ("the '252 patent"; Exhibit G hereto); and 7,179,483 ("the '483 patent"; Exhibit H hereto).

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over the defendants by virtue of the fact that, *inter alia*, each defendant has committed, or actively induced, encouraged, aided, or abetted patent infringement with knowledge that it is in contravention of Watson's rights.

7. This Court has personal jurisdiction over defendants because each defendant has sufficient minimum contacts with the forum as a result of business conducted within the State of Delaware. Upon information and belief, each defendant is incorporated, and registered and authorized to do business in the State of Delaware. Defendants—directly or through subsidiaries, intermediaries, or collaborators—ship, distribute, offer for sale, sell, import, advertise, and/or make generic drug products throughout the United States and the State of Delaware.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS COMMON TO ALL COUNTS

9. Watson is the owner of New Drug Application ("NDA") No. 21-351, which was approved by the Food and Drug Administration ("FDA") for the manufacture and sale of Oxytrol®, a transdermal film extended-release containing oxybutynin, 3.9 mg/24 hr for the treatment of overactive bladder.

10. On information and belief, Barr Laboratories, Inc. is a wholly-owned subsidiary of Barr Pharmaceuticals, Inc.

11. Barr Laboratories, Inc. submitted Abbreviated New Drug Application ("ANDA") No. 90-526 ("Barr's ANDA") to the FDA under § 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, importation, sale and/or offer for sale of Oxybutynin transdermal system extended release, 3.9 mg/24 hr ("ANDA product").

12. Barr Laboratories, Inc. sent Watson Laboratories, Inc., Watson Pharmaceuticals, Inc. and TheraTech, Inc. (hereinafter "TheraTech") a "Notification of Certification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act" dated September 11, 2008 for the '839 patent; the '010 patent; the '441 patent; the '249 patent; the '250 patent; the '251 patent; the '252 patent; and the '483 patent, regarding its ANDA product ("Notice Letter").

13. Following receipt of Barr's Notice Letter, Watson requested Barr's ANDA and samples from each lot of the ANDA product. To date, Watson has not received Barr's ANDA or any samples.

FIRST COUNT
(Infringement of the '839 Patent)

14. Watson repeats and realleges paragraphs 1 through 13 above as if fully set forth herein.

15. The '839 patent, entitled "Triacetin as a penetration enhancer for transdermal delivery of a basic drug," was duly and legally issued on February 11, 1997. The '839 patent claims, *inter alia,* methods of enhancing the rate of transdermal penetration and matrix patches for transdermal administration of oxybutynin.

16. Pursuant to 21 U.S.C. § 355(b)(1), the '839 patent is listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the *Orange Book*") as covering Watson's Oxytrol® drug product.

17. Upon information and belief, Barr filed a paragraph IV certification for the '839 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA product before the expiration of the '839 patent.

18. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21

C.F.R. §§ 314.95(c)(6)(i)-(ii).

19. Upon information and belief, as of the date of the Notice Letter (September 11, 2008), Barr was aware of the statutory provisions and regulations referred to in paragraph 18, above.

20. Upon information and belief, Barr had actual and constructive notice of the '839 patent.

21. Barr's Notice Letter stated that the ANDA product does not infringe the '839 patent. Nevertheless, the Notice Letter provided Watson with insufficient information regarding the ANDA product that is the subject of Barr's ANDA. Until Watson receives sufficient information from Barr, Watson cannot fully evaluate, confirm or test the correctness of Barr's certification that the '839 patent has not and would not be infringed.

22. Upon information and belief, therefore, Watson alleges that the submission to the FDA of Barr's ANDA with a paragraph IV certification for the '839 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '839 patent is an act of infringement, including direct, inducement of and/or contributory infringement, by Barr of one or more claims of the '839 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr commercially manufactures, uses, offers to sell, sells, or imports any ANDA product, or induces or contributes to any such conduct, it would further infringe the '839 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

23. Upon information and belief, Watson alleges that Barr's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of Barr's ANDA, will infringe one or more claims of the '839 patent.

24. The acts of infringement set forth above will cause Watson irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Infringement of the '010 Patent)

25. Watson repeats and realleges paragraphs 1 through 13 above as if fully set forth herein.

26. The '010 patent, entitled "Triacetin as a penetration enhancer for transdermal delivery of a basic drug," was duly and legally issued on November 10, 1998. The '010 patent claims, *inter alia,* methods of enhancing the rate of transdermal penetration and matrix patches for transdermal administration of oxybutynin.

27. Pursuant to 21 U.S.C. § 355(b)(1), the '010 patent is listed the *Orange Book* as covering Watson's Oxytrol® drug product.

28. Upon information and belief, Barr filed a paragraph IV certification for the '010 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA product before the expiration of the '010 patent.

29. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why

the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

30. Upon information and belief, as of the date of the Notice Letter (September 11, 2008), Barr was aware of the statutory provisions and regulations referred to in paragraph 29, above.

31. Upon information and belief, Barr had actual and constructive notice of the '010 patent.

32. Barr's Notice Letter stated that the ANDA product does not infringe the '010 patent. Nevertheless, the Notice Letter provided Watson with insufficient information regarding the ANDA product that is the subject of Barr's ANDA. Until Watson receives sufficient information from Barr, Watson cannot fully evaluate, confirm or test the correctness of Barr's certification that the '010 patent has not and would not be infringed.

33. Upon information and belief, therefore, Watson alleges that the submission to the FDA of Barr's ANDA with a paragraph IV certification for the '010 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '010 patent is an act of infringement, including direct, inducement of and/or contributory infringement, by Barr of one or more claims of the '010 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr commercially manufactures, uses, offers to sell, sells, or imports any ANDA product, or induces or contributes to any such conduct, it would further infringe the '010 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

34. Upon information and belief, Watson alleges that Barr's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of Barr's ANDA, will infringe one or more claims of the '010 patent.

35. The acts of infringement set forth above will cause Watson irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Infringement of the '441 Patent)

36. Watson repeats and realleges paragraphs 1 through 13 above as if fully set forth herein.

37. The '441 patent, entitled "Compositions and methods for minimizing adverse drug experiences associated with oxybutynin therapy," was duly and legally issued on June 1, 2004. The '441 patent claims, *inter alia,* methods of treating with oxybutynin a subject having overactive bladder while minimizing an anticholinergic or antimuscarinic adverse drug experience associated with said oxybutynin treatment therapy, and transdermal patches that minimize an anticholinergic or antimuscarinic adverse drug experience associated with the administration of oxybutynin.

38. Pursuant to 21 U.S.C. § 355(b)(1), the '441 patent is listed in the *Orange Book* as covering Watson's Oxytrol® drug product.

39. Upon information and belief, Barr filed a paragraph IV certification for the '441 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA product before the expiration of the '441 patent.

40. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

41. Upon information and belief, as of the date of the Notice Letter (September 11, 2008), Barr was aware of the statutory provisions and regulations referred to in paragraph 40, above.

42. Upon information and belief, Barr had actual and constructive notice of the '441 patent.

43. Barr alleged in its Notice Letter that the '441 patent is invalid.

44. Barr's Notice Letter does not include a full and detailed statement of the bases or grounds for that invalidity allegation. Barr failed to comply with the statutory provisions and regulations referred to in paragraph 40, above.

45. Barr's Notice Letter stated that the ANDA product does not infringe the '441 patent. Nevertheless, the Notice Letter provided Watson with insufficient information regarding the ANDA product that is the subject of Barr's ANDA. Until Watson receives sufficient information from Barr, Watson cannot fully evaluate, confirm or test the correctness of

Barr's certification that the '441 patent has not and would not be infringed.

46. Upon information and belief, therefore, Watson alleges that the submission to the FDA of Barr's ANDA with a paragraph IV certification for the '441 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '441 patent is an act of infringement, including direct, inducement of and/or contributory infringement, by Barr of one or more claims of the '441 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr commercially manufactures, uses, offers to sell, sells, or imports any ANDA product, or induces or contributes to any such conduct, it would further infringe the '441 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Upon information and belief, Watson alleges that Barr's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of Barr's ANDA, will infringe one or more claims of the '441 patent.

48. The acts of infringement set forth above will cause Watson irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

FOURTH COUNT
(Infringement of the '249 Patent)

49. Watson repeats and realleges paragraphs 1 through 13 above as if fully set forth herein.

50. The '249 patent, entitled "Compositions and methods for minimizing adverse drug experiences associated with oxybutynin therapy," was duly and legally issued on July 25, 2006. The '249 patent claims, *inter alia,* methods of treating with oxybutynin a subject having overactive bladder while minimizing an anticholinergic or antimuscarinic adverse drug experience associated with said oxybutynin treatment therapy, and transdermal patches that

minimize an anticholinergic or antimuscarinic adverse drug experience associated with the administration of oxybutynin.

51. Pursuant to 21 U.S.C. § 355(b)(1), the '249 patent is listed in the *Orange Book* as covering Watson's Oxytrol® drug product.

52. Upon information and belief, Barr filed a paragraph IV certification for the '249 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA product before the expiration of the '249 patent.

53. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

54. Upon information and belief, as of the date of the Notice Letter (September 11, 2008), Barr was aware of the statutory provisions and regulations referred to in paragraph 53, above.

55. Upon information and belief, Barr had actual and constructive notice of the '249 patent.

56. Barr alleged in its Notice Letter that the '249 patent is invalid.

57. Barr's Notice Letter does not include a full and detailed statement of the bases or grounds for that invalidity allegation. Barr failed to comply with the statutory provisions and regulations referred to in paragraph 53, above.

58. Barr's Notice Letter stated that the ANDA product does not infringe the '249 patent. Nevertheless, the Notice Letter provided Watson with insufficient information regarding the ANDA product that is the subject of Barr's ANDA. Until Watson receives sufficient information from Barr, Watson cannot fully evaluate, confirm or test the correctness of Barr's certification that the '249 patent has not and would not be infringed.

59. Upon information and belief, therefore, Watson alleges that the submission to the FDA of Barr's ANDA with a paragraph IV certification for the '249 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '249 patent is an act of infringement, including direct, inducement of and/or contributory infringement, by Barr of one or more claims of the '249 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr commercially manufactures, uses, offers to sell, sells, or imports any ANDA product, or induces or contributes to any such conduct, it would further infringe the '249 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

60. Upon information and belief, Watson alleges that Barr's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of Barr's ANDA, will infringe one or more claims of the '249 patent.

61. The acts of infringement set forth above will cause Watson irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

FIFTH COUNT
(Infringement of the '250 Patent)

62. Watson repeats and realleges paragraphs 1 through 13 above as if fully set forth herein.

63. The '250 patent, entitled "Compositions and methods for minimizing adverse drug experiences associated with oxybutynin therapy," was duly and legally issued on July 25, 2006. The '250 patent claims, *inter alia,* methods of treating with oxybutynin a subject having overactive bladder while minimizing an anticholinergic or antimuscarinic adverse drug experience associated with said oxybutynin treatment therapy, and transdermal patches that minimize an anticholinergic or antimuscarinic adverse drug experience associated with the administration of oxybutynin.

64. Pursuant to 21 U.S.C. § 355(b)(1), the '250 patent is listed in the *Orange Book* as covering Watson's Oxytrol® drug product.

65. Upon information and belief, Barr filed a paragraph IV certification for the '250 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA product before the expiration of the '250 patent.

66. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why

the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

67. Upon information and belief, as of the date of the Notice Letter (September 11, 2008), Barr was aware of the statutory provisions and regulations referred to in paragraph 66, above.

68. Upon information and belief, Barr had actual and constructive notice of the '250 patent.

69. Barr alleged in its Notice Letter that the '250 patent is invalid.

70. Barr's Notice Letter does not include a full and detailed statement of the bases or grounds for that invalidity allegation. Barr failed to comply with the statutory provisions and regulations referred to in paragraph 66, above.

71. Barr's Notice Letter stated that the ANDA product does not infringe the '250 patent. Nevertheless, the Notice Letter provided Watson with insufficient information regarding the ANDA product that is the subject of Barr's ANDA. Until Watson receives sufficient information from Barr, Watson cannot fully evaluate, confirm or test the correctness of Barr's certification that the '250 patent has not and would not be infringed.

72. Upon information and belief, therefore, Watson alleges that the submission to the FDA of Barr's ANDA with a paragraph IV certification for the '250 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '250 patent is an act of infringement, including direct, inducement of and/or contributory infringement, by Barr of one or more claims of the '250 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr commercially manufactures, uses,

offers to sell, sells, or imports any ANDA product, or induces or contributes to any such conduct, it would further infringe the '250 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

73. Upon information and belief, Watson alleges that Barr's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of Barr's ANDA, will infringe one or more claims of the '250 patent.

74. The acts of infringement set forth above will cause Watson irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

SIXTH COUNT
(Infringement of the '251 Patent)

75. Watson repeats and realleges paragraphs 1 through 13 above as if fully set forth herein.

76. The '251 patent, entitled "Compositions and methods for minimizing adverse drug experiences associated with oxybutynin therapy," was duly and legally issued on July 25, 2006. The '251 patent claims, *inter alia,* methods of treating with oxybutynin a subject having overactive bladder while minimizing an anticholinergic or antimuscarinic adverse drug experience associated with said oxybutynin treatment therapy, and transdermal patches that minimize an anticholinergic or antimuscarinic adverse drug experience associated with the administration of oxybutynin.

77. Pursuant to 21 U.S.C. § 355(b)(1), the '251 patent is listed in the *Orange Book* as covering Watson's Oxytrol® drug product.

78. Upon information and belief, Barr filed a paragraph IV certification for the '251 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA product before the expiration of the '251

patent.

79. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

80. Upon information and belief, as of the date of the Notice Letter (September 11, 2008), Barr was aware of the statutory provisions and regulations referred to in paragraph 79, above.

81. Upon information and belief, Barr had actual and constructive notice of the '251 patent.

82. Barr alleged in its Notice Letter that the '251 patent is invalid.

83. Barr's Notice Letter does not include a full and detailed statement of the bases or grounds for that invalidity allegation. Barr failed to comply with the statutory provisions and regulations referred to in paragraph 79, above.

84. Barr's Notice Letter stated that the ANDA product does not infringe the '251 patent. Nevertheless, the Notice Letter provided Watson with insufficient information regarding the ANDA product that is the subject of Barr's ANDA. Until Watson receives

sufficient information from Barr, Watson cannot fully evaluate, confirm or test the correctness of Barr's certification that the '251 patent has not and would not be infringed.

85. Upon information and belief, therefore, Watson alleges that the submission to the FDA of Barr's ANDA with a paragraph IV certification for the '251 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '251 patent is an act of infringement, including direct, inducement of and/or contributory infringement, by Barr of one or more claims of the '251 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr commercially manufactures, uses, offers to sell, sells, or imports any ANDA product, or induces or contributes to any such conduct, it would further infringe the '251 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

86. Upon information and belief, Watson alleges that Barr's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of Barr's ANDA, will infringe one or more claims of the '251 patent.

87. The acts of infringement set forth above will cause Watson irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
(Infringement of the '252 Patent)

88. Watson repeats and realleges paragraphs 1 through 13 above as if fully set forth herein.

89. The '252 patent, entitled "Compositions and methods for minimizing adverse drug experiences associated with oxybutynin therapy," was duly and legally issued on July 25, 2006. The '252 patent claims, *inter alia,* methods of treating with oxybutynin a subject having overactive bladder while minimizing an anticholinergic or antimuscarinic adverse drug

experience associated with said oxybutynin treatment therapy, and transdermal patches that minimize an anticholinergic or antimuscarinic adverse drug experience associated with the administration of oxybutynin.

90. Pursuant to 21 U.S.C. § 355(b)(1), the '252 patent is listed in the *Orange Book* as covering Watson's Oxytrol® drug product.

91. Upon information and belief, Barr filed a paragraph IV certification for the '252 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA product before the expiration of the '252 patent.

92. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

93. Upon information and belief, as of the date of the Notice Letter (September 11, 2008), Barr was aware of the statutory provisions and regulations referred to in paragraph 92, above.

94. Upon information and belief, Barr had actual and constructive notice of the '252 patent.

95. Barr alleged in its Notice Letter that the '252 patent is invalid.

96. Barr's Notice Letter does not include a full and detailed statement of the bases or grounds for that invalidity allegation. Barr failed to comply with the statutory provisions and regulations referred to in paragraph 92, above.

97. Barr's Notice Letter stated that the ANDA product does not infringe the '252 patent. Nevertheless, the Notice Letter provided Watson with insufficient information regarding the ANDA product that is the subject of Barr's ANDA. Until Watson receives sufficient information from Barr, Watson cannot fully evaluate, confirm or test the correctness of Barr's certification that the '252 patent has not and would not be infringed.

98. Upon information and belief, therefore, Watson alleges that the submission to the FDA of Barr's ANDA with a paragraph IV certification for the '252 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '252 patent is an act of infringement, including direct, inducement of and/or contributory infringement, by Barr of one or more claims of the '252 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr commercially manufactures, uses, offers to sell, sells, or imports any ANDA product, or induces or contributes to any such conduct, it would further infringe the '252 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

99. Upon information and belief, Watson alleges that Barr's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of Barr's ANDA, will infringe one or more claims of the '252 patent.

100. The acts of infringement set forth above will cause Watson irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

EIGHTH COUNT
(Infringement of the '483 Patent)

101. Watson repeats and realleges paragraphs 1 through 13 above as if fully set forth herein.

102. The '483 patent, entitled "Compositions and methods for transdermal oxybutynin therapy," was duly and legally issued on February 20, 2007. The '483 patent claims, *inter alia,* methods of treating with oxybutynin a subject having overactive bladder while minimizing an anticholinergic or antimuscarinic adverse drug experience associated with said oxybutynin treatment therapy.

103. Pursuant to 21 U.S.C. § 355(b)(1), the '483 patent is listed in the *Orange Book* as covering Watson's Oxytrol® drug product.

104. Upon information and belief, Barr filed a paragraph IV certification for the '483 patent in its ANDA to obtain approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of its ANDA product before the expiration of the '483 patent.

105. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include

"(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

106. Upon information and belief, as of the date of the Notice Letter (September 11, 2008), Barr was aware of the statutory provisions and regulations referred to in paragraph 105, above.

107. Upon information and belief, Barr had actual and constructive notice of the '483 patent.

108. Barr alleged in its Notice Letter that the '483 patent is invalid.

109. Barr's Notice Letter does not include a full and detailed statement of the bases or grounds for that invalidity allegation. Barr failed to comply with the statutory provisions and regulations referred to in paragraph 105, above.

110. Barr's Notice Letter stated that the ANDA product does not infringe the '483 patent. Nevertheless, the Notice Letter provided Watson with insufficient information regarding the ANDA product that is the subject of Barr's ANDA. Until Watson receives sufficient information from Barr, Watson cannot fully evaluate, confirm or test the correctness of Barr's certification that the '483 patent has not and would not be infringed.

111. Upon information and belief, therefore, Watson alleges that the submission to the FDA of Barr's ANDA with a paragraph IV certification for the '483 patent and for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of a drug product before the expiration of the '483 patent is an act of infringement, including direct, inducement of and/or contributory infringement, by Barr of one or more claims of the '483

patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Barr commercially manufactures, uses, offers to sell, sells, or imports any ANDA product, or induces or contributes to any such conduct, it would further infringe the '483 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

112. Upon information and belief, Watson alleges that Barr's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA that are the subject of Barr's ANDA, will infringe one or more claims of the '483 patent.

113. The acts of infringement set forth above will cause Watson irreparable harm for which it has no adequate remedy at law, unless defendants are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, plaintiff respectfully requests the following relief:

(a) A judgment declaring that the '839 patent; the '010 patent; the '441 patent; the '249 patent; the '250 patent; the '251 patent; the '252 patent; and the '483 patent remain valid and enforceable;

(b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Barr's ANDA with a paragraph IV certification to obtain approval for the commercial manufacture, use, importation, sale and/or offer for sale in the United States of the ANDA product was an act of infringement of the '839 patent; the '010 patent; the '441 patent; the '249 patent; the '250 patent; the '251 patent; the '252 patent; and the '483 patent by Barr;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the ANDA product that is the subject of Barr's ANDA shall be no earlier than the date on which the last of the '839 patent; the '010 patent; the '441 patent; the '249 patent; the '250 patent; the '251 patent; the '252 patent; and the '483 patent expires;

(d) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States or importation into the United States, of the ANDA product that is the subject of Barr's ANDA until the expiration of the last of the '839 patent; the '010 patent; the '441 patent; the '249 patent; the '250 patent; the '251 patent; the '252 patent; and the '483 patent;

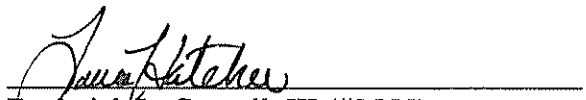
(e) A judgment declaring that, pursuant to 21 CFR 314.94(a)(12)(viii)(A), Barr amend its ANDA and convert its paragraph IV certifications to paragraph III certifications for the '839 patent; the '010 patent; the '441 patent; the '249 patent; the '250 patent; the '251 patent; the '252 patent, and the '483 patent;

(f) A judgment awarding Watson damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if defendants commercially manufacture, use, offer for sale, sell or import any product that infringes of the '839 patent; the '010 patent; the '441 patent; the '249 patent; the '250 patent; the '251 patent; the '252 patent; or the '483 patent;

(g) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Watson its attorneys' fees;

(h) A judgment awarding Watson its costs and expenses in this action; and

(i) A judgment awarding Watson such other and further relief as this Court may deem just and proper.



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